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Attorneys for Defendant
VARIAN MEDICAL SYSTEMS, INC.

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

UNIVERSITY OF PITTSBURGH OF THE COMMONWEALTH SYSTEM OF HIGHER EDUCATION d/b/a UNIVERSITY OF PITTSBURGH, a Pennsylvania non-profit corporation (educational),

Plaintiff,

v.

VARIAN MEDICAL SYSTEMS, INC., a Delaware corporation,

Defendant.

Case No. CV 08-02973 MMC

DECLARATION OF MATTHEW H. POPPE IN SUPPORT OF VARIAN'S MOTION TO TRANSFER ACTION TO U.S. DISTRICT COURT FOR WESTERN DISTRICT OF PENNSYLVANIA

Date: August 1, 2008
Time: 9:00 a.m.
Courtroom: 7, 19th Floor

I, Matthew H. Poppe, declare:

1. I am a partner in the law firm of Orrick, Herrington & Sutcliffe LLP ("Orrick"), counsel of record for defendant Varian Medical Systems, Inc. ("Varian") in this action and in *University of Pittsburgh v. Varian Medical Systems, Inc.*, Case No. 2:07-cv-00491-AJS, in the Western District of Pennsylvania (the "Penn. Case"). I am licensed to practice law in the State of California. I have personal knowledge of the facts stated herein, except where otherwise stated, and I could and would testify to those facts if called as a witness.

2. In the Penn. case, the court issued a Case Management Order setting close of fact discovery on October 5, 2007 and a claim construction hearing on November 29, 2007. Those dates held firm, except for certain discrete items of discovery that the Court allowed to proceed after the fact discovery deadline.

3. On June 12, 2008, I attended a mediation in the Penn. case. The court in the Penn. case had previously held Plaintiff University of Pittsburgh ("UPitt") in contempt in connection with a settlement conference. The mediation was scheduled pursuant to a court order permitting UPitt to purge itself of contempt if it engaged in a mediation subject to certain conditions. The mediation was held in Pittsburgh before a paid mediator.

4. On October 19, 2007, UPitt filed a 40-page opening claim construction brief and 28 exhibits in the Penn. case. On November 2, 2007, Varian filed a 55-page opening brief and 20 exhibits. On November 9, 2007, UPitt filed a 16-page reply brief. Varian and UPitt also exchanged claim construction tutorials in the form of animated videos and slides containing text and graphics.

5. On November 29, 2007, I attended an all-day claim construction hearing in the Penn. Case before the special master in Pittsburgh. Attending with me on behalf of Varian were William L. Anthony, Esq. and Zheng (Jen) Liu, Esq. of Orrick; our local counsel, Henry Sneath, Esq.; Varian's in-house counsel, Keith Askoff, Esq.; and two technical experts. UPitt was represented at the hearing by outside counsel Dan Johnson, Esq., John Zele, Esq., and Rita Tautkus, Esq.; in-house representatives Laura Hillock, Esq. and Theresa Colecchia; inventor Dr. Joel Greenberger; and a technical expert. During the hearing, opening statements and live

tutorials were presented. The parties then each put on live expert testimony, including cross-examination. Finally, the special master heard extensive oral argument by counsel. The special master and his assistant were paid an hourly rate for their time reviewing the parties' papers and attending the hearing. The case was dismissed before a claim construction ruling issued.

6. Varian did not object to litigating the Penn. Case in the Western District of Pennsylvania.

7. Varian deposed 15 witnesses in connection with the Penn. Case. Of those, 12 witnesses were deposed in Pittsburgh. Of the remaining three witnesses, one was deposed in Washington, D.C. and one in Atlanta, Georgia. One of Varian's witnesses, Peter Munro, was also deposed in Pittsburgh. A second Varian witness, Reto Glettig, also flew to the United States from Switzerland for a deposition. Two other Varian witnesses deposed by UPitt, John Coats and Richard Morse, reside on the east coast. In addition, one of Varian's experts, Dr. James Balter, resides in Ann Arbor, Michigan. Only two non-parties who were deposed in this action, Majid Riaziat and Dr. Karun Shimoga, reside in California.

8. Each of the parties retained local counsel in Pittsburgh in connection with the prior action. UPitt used attorneys in the Pittsburgh office of Morgan, Lewis & Bockius LLP, while Varian used attorneys at Picadio Sneath Miller & Norton, P.C. Varian's local counsel was actively involved in the prior case, appearing at hearings and taking several depositions. Varian's local counsel maintains copies of produced documents and deposition transcripts from the prior action in their office. The Pittsburgh office of Morgan, Lewis & Bockius LLP served as the site for the *Markman* hearing and at least two depositions in the Penn. case.

9. Attached hereto as Exhibit A is a true and correct copy of an article entitled "University Tries New Venue In Suit Against Varian," that appeared on the IP Law 360 web site on or about June 18, 2008, at http://ip.law360.com/Secure/ViewArticle.aspx?id=59582.

10. Attached hereto as Exhibit B is a true and correct copy of UPitt's Disclosure of Asserted Claims and Infringement Contentions Pursuant to LPR 3.2, filed by UPitt in the Penn. Case on or about June 15, 2007.

/ / /

11. Attached hereto as Exhibit C is a true and correct copy of the transcript of the claim construction hearing in the Penn. case (condensed version).

12. Attached hereto as Exhibit D is a true and correct copy of the original application corresponding to U.S. Patent No. 5,784,431, which shows the Pittsburgh address of Richard V. Westerhoff, Esq. as of October 29, 1996.

13. Attached hereto as Exhibit E is a true and correct copy of the original application corresponding to U.S. Patent No. 5,727,554, which shows the Pittsburgh address or Richard V. Westerhoff, Esq., as of September 19, 1996.

14. Attached hereto as Exhibit F is a true and correct copy of excerpts from the deposition of Peter Munro, taken on October 18, 2007 in the Penn. Case.

15. Attached hereto as Exhibit G is a true and correct copy of excerpts from the deposition of Sam Castellino, taken on October 16, 2007 in the Penn. Case.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed in Menlo Park, California on June 27, 2008.

/s/ Matthew H. Poppe
Matthew H. Poppe

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the DECLARATION OF MATTHEW H. POPPE IN SUPPORT OF VARIAN'S MOTION TO TRANSFER ACTION TO U.S. DISTRICT COURT FOR WESTERN DISTRICT OF PENNSYLVANIA was served upon the University of Pittsburgh, through its counsel, via:

______	Hand-Delivery
______	Facsimile
______	First Class, US Mail, Postage Prepaid
______	Certified Mail-Return Receipt Requested
___X___	ECF Electronic Service
______	Overnight Delivery

at the following addresses:

Rita E. Tautkus
Morgan Lewis & Bockius, LLP
One Market – Spear Street Tower
San Francisco, CA 94105
rtautkus@morganlewis.com

Dated: June 27, 2008

/s/ *Matthew H. Poppe*
Matthew H. Poppe

EXHIBIT A

IP LAW360

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Phone: +1 212 537 6331 | Fax: +1 212 537 6371 | customerservice@portfoliomedia.com

University Tries New Venue In Suit Against Varian

6/18/2008 --- The University of Pittsburgh filed suit Monday in California against Varian Medical Systems Inc. over patents related to radiation treatment on the same day it lost the right to pursue a similar case against the company in Pennsylvania.

The university filed the suit in the U.S. District Court for the Northern District of California claiming Varian's image-guided radiation therapy technology violates two of the school's patents.

The suit targets several products at the Palo Alto, Calif.-based company, including its widely distributed Trilogy line, said Daniel Johnson, lead counsel for the plaintiff.

Spencer Sias, vice president of corporate communications and investor relations for Varian, said only that the company believed the suit had no merit and planned to fight it vigorously.

U.S. Patent Number 5,727,554 covers an apparatus that responds to a patient's movement during treatment or diagnosis. And U.S. Patent Number 5,784,431 covers an apparatus used to match X-ray images with reference images, according to court documents.

The university first asserted the patents against Varian in April 2007 in the U.S. District Court for the Western District of Pennsylvania. But the judge dismissed that case. Carnegie Mellon University still retained some rights in the patent and thus needed to be a party to the suit, the court found.

The plaintiff tried last year to add Carnegie Mellon to the case, but the court ruled that the time for adding plaintiffs had passed, noting that discovery in the case had closed in October.

A special master appointed in the case recommended in March that the court grant Varian's motion for summary judgment based on the plaintiff's lack of standing, and the court entered a final judgment on Monday dismissing the suit with prejudice.

The university appealed the ruling and brought the second suit in California after obtaining a formal assignment from Carnegie Mellon for the patents-in-suit, according to court records.

The patents at issue are U.S. Patent Numbers 5,727,554 and 5,784,431.

The University of Pittsburgh is represented in this matter by attorneys from

Morgan Lewis & Bockius LLP.

Counsel information for Varian was not immediately available. The company was represented in the Pennsylvania matter by attorneys from Orrick Herrington & Sutcliffe LLP and Picadio, Sneath, Miller & Norton.

The case is University of Pittsburgh of the Commonwealth System of Higher Education v. Varian Medical Systems Inc., case number 08-02973 in the U.S. District Court for the Northern District of California.

The Pennsylvania suit is University of Pittsburgh v. Varian Medical Systems Inc., case number 07-00491 in the U.S. District Court for the Western District of Pennsylvania.

EXHIBIT B

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

UNIVERSITY OF PITTSBURGH Plaintiff and Counterclaim Defendant, v. VARIAN MEDICAL SYSTEMS, INC. Defendant and Counterclaimant.	Civil Action No. 2:07-CV-00491-AJS Judge Arthur J. Schwab

DISCLOSURE OF ASSERTED CLAIMS AND INFRINGEMENT CONTENTIONS PURSUANT TO LPR 3.2

Pursuant to Local Patent Rule 3.2, Plaintiff University of Pittsburgh ("UPitt") hereby provides the following Disclosure of Asserted Claims and Infringement Contentions with respect to U.S. Patent No. 5,727,554 ("the '554 patent") and U.S. Patent No. 5,784,431 ("the '431 patent"). Discovery in this case has just begun. UPitt reserves the right to revise and supplement this Disclosure as additional information becomes known.

A. CLAIMS ASSERTED

Based on the information known to it at this time, Plaintiff UPitt believes that at least the following claims are infringed:

U.S. Patent No. 5,727,554: Claims 20-22

U.S. Patent No. 5,784,431: Claims 21 and 26

As noted above, discovery in this case is ongoing and UPitt reserves the right to revise and/or supplement the asserted claims.

B. ACCUSED INSTRUMENTALITIES

Based on the information known to it at this time, Plaintiff UPitt believes that at least the following claims are infringed:

1. U.S. Patent No. 5,727,554

Claim 20 of the '554 patent is infringed by Varian's RPM Respiratory Gating system, which may be sold as part of Clinac linear accelerator systems and Trilogy Stereotactic systems.

Claim 21 of the '554 patent is infringed by Varian's RPM Respiratory Gating system, which may be sold as part of Clinac linear accelerator systems and Trilogy Stereotactic systems.

Claim 22 of the '554 patent is infringed by Varian's RPM Respiratory Gating system, which may be sold as part of Clinac linear accelerator systems and Trilogy Stereotactic systems.

2. U.S. Patent No. 5,784,431

Claim 21 of the '431 patent is infringed by Varian's Clinac linear accelerator systems that include the On-Board Imager and the PortalVision imager, and Varian's Trilogy Stereotactic systems.

Claim 26 of the '431 patent is infringed by Varian's Clinac linear accelerator systems that include the On-Board Imager and the PortalVision imager, Varian's Trilogy Sterotactic systems, and in addition to the systems by themselves, either one of the aforementioned systems in combination with Varian's Acuity simulation and verification systems.

Discovery in this case is ongoing and UPitt reserves the right to revise and/or supplement the accused instrumentalities.

C. CHART OF ASSERTED CLAIMS

1. U.S. Patent No. 5,727,554

Claim 20	Description of Claimed Function of §112(6) Elements	Varian's RPM Respiratory Gating System
20. Apparatus responsive to movement of a patient positioned on a patient positioning assembly, said apparatus comprising:		As currently understood, the RPM Respiratory Gating system is responsive to movement of a patient positioned on a treatment table of Varian Clinac and Trilogy linear accelerators.
camera means generating digital image signals representative of an image of said patient; and		As currently understood, the RPM Respiratory Gating system includes a charge-coupled device (CCD) tracking camera and a multi-channel synchronized video acquisition board.
processing means comprising	The "processing means" is an element interpreted according to 35 U.S.C. § 112, ¶ 6. The function of the element is processing.	As currently understood, the RPM Respiratory Gating systems include a PC Workstation that performs processing.
means determining movement of said patient from said digital image signals, including movement associated with breathing by said patient, and	The "means determining movement ..." is an element interpreted according to 35 U.S.C. § 112, ¶ 6. The function of the element is determining movement of the patient from the aforementioned digital image signals. The determined patient movement includes movement associated with the patient's breathing.	As currently understood, the PC Workstation of Varian's RPM Respiratory Gating system determines movement of the patient from digital image signals, including movement associated with patient breathing.

gating means generating gating signals synchronized with said movement associated with breathing by said patient.	The "gating means" is an element interpreted according to 35 U.S.C. § 112, ¶ 6. The function of the element is generating gating signals synchronized with the aforementioned movement associated with the patient's breathing.	As currently understood, the PC Workstation of Varian's RPM Respiratory Gating system generates gating signals synchronized with the movement associated with patient breathing. The RPM Respiratory Gating system further includes a gating switchbox.

Claim 21	Description of Claimed Function of §112(6) Elements	Varian's RPM Respiratory Gating System
21. The apparatus of claim 20, wherein said camera means generates said digital image signals representing an image of at least one fiducial on said patient, and said means determining movement of said patient includes means determining movement of said at least one fiducial.	The "means determining movement of said at least one fiducial" is an element interpreted according to 35 U.S.C. § 112, ¶ 6. The function of the element is determining movement of the at least one fiducial on the patient.	As currently understood, the CCD tracking camera and video acquisition board of Varian's RPM Respiratory Gating system generates digital image signals representing an image of at least one fiducial on the patient. The PC Workstation of the RPM Respiratory Gating system determines movement of the fiducials.

Claim 22	Description of Claimed Function of §112(6) Elements	Varian's RPM Respiratory Gating System
22. The apparatus of claim 20 adapted for use during treatment of said patient with a radiation beam generated by a beam generator,		As currently understood, the RPM Respiratory Gating system is intended to be used with a radiation beam generated by a beam generator, such as Clinac linear accelerators.
wherein said gating means comprises means generating said gating signals synchronized to actuate said beam generator in synchronism with patient breathing.	The "means generating said gating signals …" is an element interpreted according to 35 U.S.C. § 112, ¶ 6. The function of the element is generating the gating signals synchronized to actuate the beam generator in synchronism with patient breathing.	As currently understood, the PC Workstation of Varian's RPM Respiratory Gating system generates gating signals synchronized to actuate the beam generator in synchronism with patient breathing. The RPM Respiratory Gating system further includes a gating switchbox.

Each of claims 20-22 are believed to be infringed literally. To the extent that Defendant alleges that one or more elements of any claim is not present in an accused instrumentality, Plaintiff UPitt reserves the right establish infringement under the doctrine of equivalents.

2. U.S. Patent No. 5,784,431

Claim 21	Description of Claimed Function of §112(6) Elements	Varian Clinac and Trilogy systems with On-Board Imager and PortalVision imager
21. Apparatus for matching portal images to control radiotherapy/diagnosis equipment, said apparatus comprising:		As currently understood, the Clinac and Trilogy systems match portal images for system control.
means digitizing successive portal images to generate successive sets of digital portal image signals (DPIS); and	The "means digitizing successive portal images ..." is an element interpreted according to 35 U.S.C. § 112, ¶ 6. The function of the element is digitizing successive portal images to generate successive sets of digital portal image signals (DPIS).	As currently understood, the Clinac and Trilogy systems include an MV image acquisition system with a digitization unit and a kV image acquisition system with a detector that digitize successive portal images to generate successive sets of digital portal image signals.
tracking means tracking movement between successive sets of DPIS.	The "tracking means" is an element interpreted according to 35 U.S.C. § 112, ¶ 6. The function of the element is tracking movement between successive sets of DPIS.	As currently understood, the On-Board Imager of the Clinac and Trilogy systems use successive images to track movements between successive sets of digital portal image signals.

Claim 26	Description of Claimed Function of §112(6) Elements	Varian Clinac and Trilogy systems with On-Board Imager and PortalVision imager
26. Apparatus for automatically matching an x-ray image with a reference image, said apparatus comprising:		As currently understood, the Clinac and Trilogy systems match x-ray images with reference images.
means digitizing said x-ray image and reference image to generate first digital image signals and second digital image signals, respectively;	The "means digitizing said x-ray image and reference image ..." is an element interpreted according to 35 U.S.C. § 112, ¶ 6. The function of the element is digitizing the x-ray image and the reference image to generate first digital image signals and second digital image signals, respectively.	As currently understood, the Clinac and Trilogy systems include an MV image acquisition system with a digitization unit and a kV image acquisition system with a detector that digitize x-ray images and reference images to generate first digital image signals and second digital image signals, respectively. The On-Board Imager can use reference images obtained from the Image Acquisition System of the Acuity simulator as digital radiographs.
processing means processing said first and second digital signals without input of any physical dimensions of any features within said images to generate matched digital image signals; and	The "processing means" is an element interpreted according to 35 U.S.C. § 112, ¶ 6. The function of the element is processing the first and second digital signals without input of any physical dimensions of any features within the images to generate matched digital image signals.	As currently understood, the On-Board Imager workstation processes the first and second digital signals without input of any physical dimensions of any features within the images to generate matched digital image signals.
display means generating a display from said matched digital image signals.	The "display means" is an element interpreted according to 35 U.S.C. § 112, ¶ 6. The function of the element is generating a display from the matched digital image signals.	As currently understood, the Clinac and Trilogy systems include an On-Board Image Monitor that displays the resulting matched images.

Each of claims 21 and 26 are believed to be infringed literally. To the extent that Defendant

alleges that one or more elements of any claim is not present in an accused instrumentality, Plaintiff UPitt reserves the right establish infringement under the doctrine of equivalents.

D. PRIORITY CLAIM TO AN EARLIER APPLICATION

The '554 patent was filed on September 19, 1996. The '431 patent was filed on October 29, 1996. Neither the '554 patent nor the '431 patent claims priority to an earlier patent application.

E. UPITT INSTRUMENTALITIES PRACTICING THE CLAIMED INVENTIONS

An experimental set-up, including cameras, digitizers, a linear accelerator gantry, and computer system, reflects each of claims 20, 21, and 22 of the '554 patent.

An experimental system, including a CCD camera grabber and computer system including a display, reflects each of claims 21 and 26.

Discovery in this case is ongoing and UPitt reserves the right to revise and/or supplement the instrumentalities practicing the claimed inventions as further information becomes available.

DATED: June 15, 2007

Allison K. Young
Daniel Johnson, Jr. (*pro hac vice*)
Rita E. Tautkus (*pro hac vice*)
Allison K. Young (*pro hac vice*)
MORGAN, LEWIS & BOCKIUS LLP
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Attorneys for Plaintiff University of Pittsburgh

CERTIFICATE OF SERVICE

I am employed in the City of Palo Alto, County of Santa Clara, State of California, I am over the age of 18 years and not a party to the within action. My business address is 2 Palo Alto Square, 3000 El Camino Real, Palo Alto, California 94306. On June 15, 2007, I caused a copy of the attached document(s) described as follows:

DISCLOSURE OF ASSERTED CLAIMS AND INFRINGEMENT CONTENTIONS PURSUANT TO LPR 3.2

to be served on:

William L. Anthony, Jr.
Matthew H. Poppe
Orrick, Herrington & Sutcliffe LLP
1000 Marsh Road
Menlo Park, CA 94025
(650) 614-7400
(650) 614-7401 (facsimile)
wanthony@orrick.com
mpoppe@orrick.com

___(BY OVERNIGHT DELIVERY) I caused each such envelope to the addressee(s) noted above, with charges fully prepaid, to be sent by overnight delivery from Palo Alto, California. I am readily familiar with the practice of Morgan, Lewis & Bockius LLP for collection and processing of correspondence for overnight delivery, said practice being that in the ordinary course of business, mail is placed with the overnight delivery service on the same day as it is placed for collection.

X_____BY ELECTRONIC MAIL) The person whose name is noted below caused to be transmitted by electronic mail each such document to the addressee(s) wanthony@orrick.com and mpoppe@orrick.com noted above.

______(BY FIRST CLASS MAIL) I caused each such envelope to the addressee(s) noted above, with postage thereon fully prepaid, to be placed in the United States mail in Palo Alto, California. I am readily familiar with the practice of Morgan, Lewis & Bockius LLP for collection and processing of correspondence for mailing, said practice being that in the ordinary course of business mail is deposited in the United States Postal Service the same date as it is placed for collection.

______(BY FACSIMILE) The person whose name is noted below caused to be transmitted by facsimile each such document to the addressee(s) noted above.

______(BY PERSONAL SERVICE) The person whose name is noted below caused to be delivered by hand each such envelope to the addressee(s) noted above.

and a courtesy copy to be served on:

Henry M. Sneath (PA ID No. 40559)
Shannon M. Clougherty (PA ID No. 88586)
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(412) 288-4000
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hsneath@psmn.com
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_____(BY OVERNIGHT DELIVERY) I caused each such envelope to the addressee(s) noted above, with charges fully prepaid, to be sent by overnight delivery from Palo Alto, California. I am readily familiar with the practice of Morgan, Lewis & Bockius LLP for collection and processing of correspondence for overnight delivery, said practice being that in the ordinary course of business, mail is placed with the overnight delivery service on the same day as it is placed for collection.

X_____(BY ELECTRONIC MAIL) The person whose name is noted below caused to be transmitted by electronic mail each such document to the addressee(s) hsneath@psmn.com and sclougherty@psmn.com noted above.

_______(BY FIRST CLASS MAIL) I caused each such envelope to the addressee(s) noted above, with postage thereon fully prepaid, to be placed in the United States mail in Palo Alto, California. I am readily familiar with the practice of Morgan, Lewis & Bockius LLP for collection and processing of correspondence for mailing, said practice being that in the ordinary course of business mail is deposited in the United States Postal Service the same date as it is placed for collection.

_______(BY FACSIMILE) The person whose name is noted below caused to be transmitted by facsimile each such document to the addressee(s) noted above.

_______(BY PERSONAL SERVICE) The person whose name is noted below caused to be delivered by hand each such envelope to the addressee(s) noted above.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct. Executed at Palo Alto, California, on June 15, 2007.

Marilyn J. Boensch

EXHIBIT C

In The Matter Of:

University Of Pittsburgh v.
Varian Medical Systems, INC.,

Claim Construction Hearing
November 29, 2007

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Pittsburgh, Pennsylvania 15219
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Word Index included with this Min-U-Script®

Page 1

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

\- - -

UNIVERSITY OF PITTSBURGH,)
)
Plaintiff,)
)
vs.) Case No.
) 2:07-CV-00491-AJS
VARIAN MEDICAL SYSTEMS, INC.,)
)
Defendant.)

\- - -

CLAIM CONSTRUCTION HEARING
Thursday, November 29, 2007

\- - -

The hearing before DONALD E. ZIEGLER, taken before me, the undersigned, Lance E. Hannaford, a Notary Public in and for the Commonwealth of Pennsylvania, at the offices of 32nd Floor, One Oxford Centre, Pittsburgh, Pennsylvania 15219, commencing at 9:00 o'clock a.m., the day and date above set forth.

\- - -

COMPUTER-AIDED TRANSCRIPTION BY
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PITTSBURGH, PENNSYLVANIA
412-281-0189

\- - -

Page 2

APPEARANCES:

On behalf of the Plaintiff:

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Morgan Lewis:
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On behalf of the Defendant:

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William Anthony, Esquire
Zheng Liu, Esquire
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Menlo Park, California 94025

Picadio Sneath Miller & Norton:
Henry M. Sneath, Esquire
4710 U.S. Steel Tower
Pittsburgh, Pennsylvania 15219

ALSO PRESENT:

Moira Cain-Mannix
Laura Hillock
Theresa Colecchia
Dr. James Balter
Dr. Steven Jiang
Dr. Joel Greenberger
Dr. Michael Schell

I-N-D-E-X

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Page 3

JUDGE ZIEGLER: This case is entitled University of Pittsburgh as plaintiff versus Varian Medical Systems, Incorporated as defendant.

Civil action No. 2:07-CV-00491 pending before Judge Schwab in United States District Court for the western district of Pennsylvania. Further pending before the special master are two motions.

The motion of the University of Pittsburgh to strike the defendant's tutorial, that motion will be denied.

There is also a motion that pertains to summary judgment raising the issue of standing.

We will of course take that matter under advisement.

Next, the parties have agreed in a case management order concerning the format for today's hearing.

As I recall in looking at it last night, in general each side is given 2.5 hours to present their respective positions.

At the outset we will begin with a 15 minute opening statement and a tutorial to be presented by each side.

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University of Pittsburgh of course as plaintiff will proceed first.

As far as I am concerned, Mr. Johnson, you can intermingle your opening statement with the tutorial, if you want to.

Whatever format you want to use for that purpose is your call.

MR. JOHNSON: My call is start with the tutorial.

And then focus on my opening remarks after that.

JUDGE ZIEGLER: You may proceed.

MR. JOHNSON: Your Honor, we will have Dr. Joel Greenberger handle the tutorial.

He has a series of animations.

JUDGE ZIEGLER: Let me say one final point.

To make certain that I receive all of the papers, motions, pleadings, that you may file in due course, I would ask you, if you would, please, could you also send me one courtesy copy in hard copy in due course?

That would be helpful.

DR. GREENBERGER: My name is Dr. Joel Greenberger. I am a radiation oncologist with the University of Pittsburgh.

I wanted to go through a background of radiation therapy and how certain problems have arisen, which we have tried to approach.

Cancer is a group of diseases in which human cells grow, mutate agressively, invade normal tissues and destroy the normal tissues as they invade.

Radio therapy, which is also called radiation therapy or x-ray therapy, teletherapy or irradiation, is one of the modalities we use to treat cancer.

Most patients are seen by at least three doctors, a surgeon, a radiation oncologist and a medical oncologist.

The goal of radiotherapy is to damage as many cancer cells in a target volume as possible while limiting the dose to nearby healthy tissues.

So as radiation oncologist, very similar to surgeons, are concerned about anatomy and targeting the tumor while protecting normal tissue.

Medical oncology is concerned with giving chemotherapy, which goes systemically through the patient and gets everywhere.

Now, when radiotherapy is delivered, what happens is radiation beams traverse the cancer cells shown here in the middle.

The goal is to kill the cancer cells and allow repopulation of that area by normal tissue.

You can see these examples of how the beam is hitting the cancer.

The beam is also traversing normal tissue at every one of its movements.

So normal tissue, normal cells are going to be damaged.

And a goal of radiotherapy is to get as high a possible dose to the tumor cells as possible without hurting the normal tissue. That ultimately translates in to hurting the patient.

X-rays have been very useful in radiotherapy.

Diagnostic x-rays in the low or kilovoltage range have been used since the early 1900's for diagnosis.

And as you can see here in this picture of a hand with a ring, some materials are radio opaque, meaning few x-rays pass through them. That is why the ring on the finger shows up brightly.

Low or kilovoltage or orthovoltage x-rays are used to take these pictures.

In the spectrum of x-ray energy, higher energy x-rays are used in treatment.

This is because they can penetrate the tissues deeper and spare the skin.

Now, the visible light range here is in the middle.

It is important to note the infrared spectrum and the x-ray spectrum cannot be seen by people.

And infrared as well as x-ray spectrum was well understood in the early '90s and was used in various types of technologies.

All of which was available at the time we began working on this problem.

Now, x-rays have a wide range of energies. The low or kilovoltage x-rays produce higher contrast images. That is why they are used in diagnostic x-rays when you go to the hospital.

Lower energy x-rays may also be used in treatment.

We use low energy kilovoltage x-rays to treat skin cancer.

This is because energy builds up in the

skin.

The higher energy x-rays penetrate deep in to the body.

They deliver better therapeutic doses. However, the quality of the image you get, when you use a high energy beam to take a picture is usually less valuable, because the difference between the bony landmarks and the air in the lung is less different.

However, I have to emphasize kilovoltage x-rays can be used in both treatment and diagnosis.

And high energy megavoltage x-rays primarily used in treatment can also be used in imaging.

Here is a picture, a high energy megavoltage image can be used to verify anatomic landmarks.

Although the difference between the rib and the lung, the heart and the trachea isn't quite as dramatic as in the kilovoltage example. Megavoltage imaging can be used.

High energy x-rays penetrate better than low energy x-rays.

And they are usually better for therapy,

although we use both high and low energy x-rays in therapy.

Now, pictured in this scenario is a patient lying on a treatment table in a radiotherapy room.

Exterior beam radiotherapy involves directly applying a treatment beam to the part of the body that requires the treatment.

It differs from chemotherapy, as I said before, which involves a chemical infusion in to the patient's body that affects the whole body.
Now, the components of the linear accelerator here are pretty much the same in all models produced by all companies.

There is a linear accelerator machine, which generates the x-rays. There is a collimator for the beam that shapes the beam.
And then there is this key component.

The gantry, which rotates like a telephone.

It looks like a telephone. It rotates.

And can move the treatment beam to any of a number of positions.

When the treatment is delivered, many components of the machine can be moved to adjust

that beam to a configuration that hits the tumor.

Now, what can we do to modify the beam?

Beam size and shape can be changed.

The cross sectional size and shape of the beam that is applied to the patients can be made thin or thick.

And this is because of the changes up here in the collimator.

There are other things we can do.

We can move the direction of the beam.

We can move this gantry, so the beam can come in at an oblique angle, or it can come in from the front or back angle.

The goal, of course, is hit the tumor and produce as much damage to the tumor while not hurting the normal tissues.

Another thing we can do is to change the dose rate.

We can have the machine essentially pump out more radiation per second or per minute than at another time.

And the higher dose rate produces greater tissue damage than a lower dose rate.

Another parameter we can control.

By modifying the time, we can give a bigger

treatment, a bigger dose.

There are problems.

When a tumor is discovered, the radiation oncologist may determine radio therapy is the best course of treatment.

Here is an example in which we have a tumor in the lung surrounded by normal lung tissue, heart, spinal cord.

At this point the treatment process has two stages.

One is called simulation or planning.

The other is called treatment.

In the simulation process, we usually use the low energy orthovoltage energy to take pictures and to define the size and shape of the beam that we ultimately want to give.

In this example, it is a circle.

There is a cross section, a size of it. A diameter.

And an angle that we want to put the machine at to deliver the treatment.

We also fractionate the treatment giving multiple smaller doses on different days.
Sometimes twice a day.

Sometimes five days a week. Sometimes over

seven weeks duration.

Every time we deliver a treatment, we run the risk of not hitting the cancer volume.

We run the risk of treating too much normal tissue.

The simulation phase is carried out using a machine called a simulator.

It usually produces a picture with a low energy orthovoltage image.

And this image is then used to match it to a treatment image.

It is important, because the simulation is carried out infrequently, whereas the treatments are carried out daily or sometimes more than once a day.

In the treatment phase, the patient is on the treatment machine.

There is a couch or bench or patient treatment platform.

And this platform can move only in a number of parameters, that are based upon the inherent movement of the machine.

The couch can move in and out.

It can move side to side.

It can move up and down.

The simulation phase image usually orthovoltage is then matched to a treatment phase image, which is taken by exposing a film or using some type of an image capture device underneath the patient opposite the beam.

And these two films are then matched.

What is important is that the matching for years certainly in 1993 was carried out by physicians looking at the two images and saying "I am on target" or "I am not".

The physician would look at the simulation film, and then this treatment phase image and see that he or she was on target.

And then approve the treatment.

One of the problems that was inherent in this situation was the problem of misalignment.

You can appreciate if the simulation was to target the tumor and the treatment phase image was off target, unless this were corrected, you could do two very bad things.

Miss part of the tumor.

Treat unnecessarily normal tissue.

Or in fact do both.

Miss tumor and treat unnecessarily normal tissue.

The more treatment fractions in which the misalignment occurred, the more we were not serving the patient as well as we could.

Because we are missing tumor and damaging normal tissue.

So the problem we had was to automate or make more efficient this process of hitting the tumor and missing normal tissue.

We had two problems that had to be overcome.

The tumors are three dimensional, they are not flat.

These images are two dimensional. The other problem is that patients are moving.

Patients are breathing.

They are twitching.

Many of them are sick, coughing, and although things look good at the time the patient is set up on the machine, there may be movement.

How do we solve this problem?

Early on, radiation oncologists compared an image taken during the simulation phase with an image taken during the treatment phase.

Estimate the differences.

And then manually control for alignment of

the beam.

Move the patient.

Move the beam.

If necessary, go back to the simulator and repeat the simulation process.

What we found was helpful was to devise a system using fiducials or markers.

These can be bright spots, reflective spots, or they can be other types of markers used as a grid in which the tumor could be estimated in its position relative to one or more fiducial markers, either fixed or moving markers during treatment to allow us to determine if the beam was on target.

In this setting, one can see here that an x-ray image taken during the first phase or simulation phase could be matched to an image taken during the second phase or the treatment phase.

This would give a better way of determining if the radiation oncology treatment was on target.

Now, computerized image matching was thought to us back in 1993 as being an ideal way to enhance this process and eventually be able to

do it quickly and much more efficiently.

A computer can be used to identify these fiducial markings in the x-ray images and objectively determine movement between the images even though these images may differ significantly in appearance.

The major problem, a major problem was breathing.

There just was no way to fix the patient on the treatment couch or the bench and allow the beam to be certainly on target all the time during a one minute or sometimes two minute treatment, if the patient is breathing.

You can appreciate from this movie, that at some points during respiration, the cancer is in the image, such as now.

And another point is out of the image.

One way that radiation oncologists solve this problem before this technique was devised was to treat a much bigger volume of tissue to be certain that the beam was in -- was hitting the tumor in all situations.

In other words, make this circle twice as big, so that the cancer would be definitely in the beam.

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Of course, the disadvantage is you needlessly are treating more normal tissue.

Early solutions involved fixing the patient.

Now, this might be possible for a head neck cancer patient in which this malleable plastic like material is used to immobilize the head, attached to the treatment couch by vice like design.

And a patient's head would not move, tumor target would not move very much.

This clearly is impractical in a situation for a tumor in the chest such as a lung cancer or esophagus cancer in which the patient has to breathe.

Now, one approach, which we took, was to use a charge couple device, CCD camera, to actually be able to watch the movement of these fiducials.

And to be able to track whether the fiducial was in the target or was out of the target.

During respiration, these markers could be followed.

And the ideal situation, which we thought

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of, was to link the data collected by the CCD detector to the machine, so you could turn the machine off, when the cancer moved out of the volume.

Turn the machine back on during respiration, when the cancer was in the field.

And in fact, this would be a situation in which the cancer is only treated when it is in the field and the respiratory cycle.

You can imagine if the beam were on, it is on now, if the beam were on at this point, you would be needlessly treating normal tissue in this area, which is out of the beam.

So in summary, the major challenges we had in radiation oncology at that point in 1993 were how to maximize dose to the tumor, minimize dose to normal tissue given two real problems. Cancers are three dimensional and people are moving.

And we chose to use the patient as the system by which to monitor where the patient is, not using the bench or not using fixed variables on the couch.

MR. JOHNSON: Thank you, Doctor.

We have now given you just an overview of

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technology involved.

Do you have questions?

JUDGE ZIEGLER: I have no questions.

Thank you, sir.

MR. JOHNSON: Then let's -- now, following the sequence, will they proceed with their tutorial, or should I do my opening?

JUDGE ZIEGLER: What is your pleasure?

MR. SNEATH: I am going to deliver an opening statement.

But if you have one --

MR. JOHNSON: I am prepared.

JUDGE ZIEGLER: Mr. Johnson, proceed with your opening statement.

MR. JOHNSON: You now had opportunity to get a general understanding of the technology. Now I want to focus on two areas.

One is just generally what the patents cover.

And then two, the law regarding claim construction.

Because I think the two in this case go hand in hand.

This is -- as you know, is a process to interpret what the claims mean.

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That interpretation is a matter of law.

We have means plus function claims here. Which has a certain meaning.

We also have basic standard meaning approaches that you have to take in order to construe these claims.

You are aware we have the two patents, the '554 and '431.

The '554 covers one aspect of the tutorial as it relates to patient movement.

'431 relates to the other aspect of the tutorial, which is the matching of the various images.

So if you look at the '554, as you just heard, the issue is how can you avoid basically destroying good tissue while at the same time ensuring you hit the tumor.

And solving the problem patient movement. This is patient movement in a number of contexts.

Not limited to breathing. It includes any type of patient movement.

And you use the fiducials in order to assist you in making that decision.

You want to do it using a computer.

Because the less guesswork you have, the more precision you will have.

As you just heard Dr. Greenberger say, we track the patient.

There are other technologies that adjusted the couch.

But the '554 tracks the patient movement and therefore enables, we believe, a much more accurate approach to solving the problem that we discussed here.

Now, the '431 concerns the problem of automatically matching various x-ray images with a reference image.

And the advantage, obviously, is the more precise the match, the more accurate you are going to be in terms of your locating of the tumor.

And you are going to have much better diagnostic as well as treatment.

Now, claim construction.

Spending a little time on the law in claim construction, because I think it is important for you to be focused on exactly what we are talking about today.

As the court knows, there is a difference

between the claims and the specification. You will hear a lot about that today.

But the law is very clear.

That the claims define the invention, and the court has to construe the claims.

Here is an example of what we mean.

We are going to offer construction of successive.

That is following an order.

Which is basically the general and commonly understood definition for that term.

You are going to hear Varian's construction. That is going to include all sorts of additional items like taking an uninterrupted sequence during a single radiation treatment.

None of that language is in the claim.

We are here to define those terms.

I want to emphasize two things.

There is a difference between defining the terms and focusing on function in a means plus function case.

That we will talk about.

But the terms themselves are given their common meaning, unless there is some reason to do otherwise.

And that reason has to be found in the specification, or in a disavowal during the patent process, none of which we will demonstrate has occurred here.

The second most and fundamental principle you have to deal with today is, and we are quoting from a recent case, which was not in our brief, I didn't realize that there would be much debate.

But since there is, I want to emphasize the following.

Our cases make clear, however, that adding limitations to claims not required by the claim terms themselves or unambiguously by the specification or prosecution history is impermissible.

We are going to be spending a lot of time telling you that Varian is attempting to do something that the federal circuit says is impermissible.

They are trying to add claim terms that are neither ambiguous nor supported by anything in the specification that would justify the adding of such terms.

Again, we cite another case that talks

about adding extraneous limitation appearing in the specification is improper.

We are going to go through a variety of these issues in the patent specification.

I am not going to go in to them now.

But I will simply say that many of the claims we are going to be talking about today -- or terms, I should say, are terms that have commonly understood meaning to someone of ordinary skill in the art.

And adding terms or trying to rewrite them in a way that is much different than the actual language of the claims is improper.

Now, let's talk about a means claim for a moment.

Means claim simply says that if a claim is expressed in a means or step, and there is not a recital of structure or material, then they look to the specification and drawings to find the relevant structure and material.

However, if there is sufficient disclosure, you don't have to look to the specification and material.

In other words, if the claim has disclosure, you don't have to look to the

specification.

We will spend a lot of time today talking about means plus function claims and what is included.

The other point to be made.

Again, these are just examples of terms we are going to go through.

What is a camera means, a display means? Those are issues we will take up.

But we are going to prove to you that, in fact, those really aren't means plus function claims.

They have a commonly understood meaning to one of ordinary skill.

And therefore, we believe that our proposed construction is the proper one.

Now, because these are means plus function claims, and we are dealing with computers, one of the issues is when you look at the specification, you find algorithms.

How do you interpret algorithms?

And what can you import from the algorithms in to the claims?

We are going to demonstrate to you that you look at the proposed algorithm, as outlined

above.

You have to define the algorithm broadly, because that is done by the federal circuit.

And you only focus on the appropriate structure necessary to carry out the function.

And we recite the Odetics case, which was not an algorithm case, but is cited in all the algorithm cases for the following proposition.

Individual components, if any, of an overall structure that corresponds to the claimed function are not claim limitations.

Rather, the claim limitation is the overall structure corresponding to the claimed function.

Now, in plain English, what that means is you have to be able to ascertain the overall operation being performed.

And the various individual elements that make up that operation in an algorithm are not part of the claim.

And we are going to show you case law that directly speaks to that.

One of the issues in this case for purpose of this hearing is how -- is addressing that particular issue.

And we cite cases -- we cited some district

court cases here, because they were as a matter of fact the clearest on the point.

But they all stand for the same proposition, which is you look -- when the court is able to identify an overall structure that performs a claim function, there is no need to delve deeper and identify the internal components of that structure.

Later on we will show you a federal circuit case where this very principle is applied.

Because what we are going to demonstrate to you today is that the argument being made, that every element of an algorithm is part of a claim is not only wrong, it is unequivocally rejected by the federal circuit.

Another principle that we are going to go through is the exclusion of a preferred embodiment.

The law is very clear that you can't have a claim construction that excludes preferred embodiment, unless there is a very unusual circumstance.

And it would require highly persuasive evidence support.

We will demonstrate to you that Varian has

proposed a claim construction that would exclude the preferred embodiment.

That it is totally inconsistent with the claim language.

And I think we will demonstrate to you that following the laws as you must, that exclusion -- the attempt to exclude in this case fiducials or artificial fiducials is improper.

Another principle you will have to deal with is the effect of dependent claims.

The dependent claims tend to -- two types of changes.

There are independent claims and dependent claims.

The dependent claims depend from the independent claim, and they usually focus on a particular area that may or may not have been called out -- has not been called out in the independent claim.

The fact that there are dependent claims that call out specific structure is evidence that the patent holder understood and knew what it was doing, when it defined the terms the way it did. It defined the claims the way it did.

So for example, when we deal with words

like fiducials, there are specific dependent claims that cover certain types of fiducials but not others.

We will point out or demonstrate to you under the law, that is evidence that the exclusionary attempt that will be made by Varian has to fail.

Finally, there is -- the defendant's brief talks about use of prior art in claim construction.

It talks about preserving validity. What it doesn't talk about is what the law is.

The law is that the doctrine of construing claims to preserve their validity, a doctrine of limited utility in any event therefore has no applicability, because it is only applied in cases where the claim term is ambiguous.

And the evidence will show -- we will demonstrate there is no ambiguity as to these claims.

That the doctrine they are trying to invoke has no application here.

In summary, we are going to demonstrate to you that the common ordinary understood plain meaning of one of ordinary skill in the art

really governs this case and should direct the court in a way in which these claims can be construed.

You heard from Dr. Greenberger.

Dr. Michael Schell will testify briefly about the standard of ordinary skill and some of the claim terms.

That is it.

JUDGE ZIEGLER: Thank you, Mr. Johnson.

Mr. Sneath.

MR. SNEATH: Thank you, your Honor.

As you know, I represent Varian along with my colleagues who are here today.

As Mr. Johnson has pointed out, we are going to be discussing two patents, your Honor.

I will discuss a few very broad concepts here and touch a little on the history of these claimed inventions in response to Dr. Greenberger's opening comments and tutorial.

Both of these patents, the '554 and '431, your Honor, were applied for in the fall of 1996.

And were issued in March and July of 1998, respectively.

We are going to be asking you to construe a

couple of dozen terms here today.

But I am sure we will touch on almost all of them specifically.

But I want to make a few general points particularly about claim construction and about the history of these patents.

This is a classic case, your Honor, of patents that have very narrow protection.

Very narrow protection on really what are purely theoretical concepts.

As opposed to real world applications of these concepts.

Dr. Greenberger's story is compelling.

And motivated, as you can see, by a real desire to treat patients.

And that is great.

But what we are here to do today is construe certain terms in these patents, and that is the real focus of the inquiry today.

They are seeking to enforce these patents against a company Varian, who in partnership with UPMC, who employs Dr. Greenberger, have established a whole number of cancer treatment centers in this region and beyond using products from my client Varian.

MR. JOHNSON: Totally irrelevant to claim construction.

JUDGE ZIEGLER: Overruled.

MR. SNEATH: I want to give a little history, because Dr. Greenberger did that. I want the same opportunity, if you don't mind. I appreciate it.

UPMC has partnered, in their words, with our client to create cancer centers using our technology the Varian products.

And these have been developed as part of the backbone of their treatment centers all around this region.

In stark contrast to that, your Honor, the Pitt inventors have inventions on paper in these patents, which have never been commercialized, never been developed, never been tested clinically.

And never put in to practice.

And so what is important is that this story about a desire to have a fully automated computer controlled system for radiology treatment has simply not come to fruition in these inventors' practice.

The story, as you heard, is that there was

an intention to create a fully automated system, where radiation oncologists program in to a computer a treatment plan.

And he would then take simulation images, as you heard described, program them in to the computer, match them up with treatment images, and have all of this programmed in to the computer to be done automatically, so that these components, that you saw in the diagrams, the gantry, the couch, the collimator that generates the beam, that all those things controlled by a computer would move automatically to accomplish the very worthwhile goal of treating only tumor and not healthy tissue.

That was the intention.

Whether due to lack of ability or otherwise, they never achieved that fully automated system.

And so what they have in the patents is a far more modest invention.

It essentially consists of a pair of computer algorithms that were designed to perform two very narrow functions.

The first in the '554 patent is what you heard mention of x-ray matching technology.

Second in the '431 patient motion detection.

When they did this back in the '90s, they entered a very crowded field because many people had already researched and developed algorithms to do the same functions.

And though they like to characterize their invention as unique and revolutionary, all they really contributed were some tweaks on some already known algorithms.

And there is no evidence that any of them work or that any of them have ever been put in to practice.

So the critical point is that these claimed inventions were narrow.

And are limited to the very specific algorithms that these inventors developed in their patents.

This is borne out by the way the patents are written, and my colleagues, as Mr. Johnson will do, are going to focus on the language.

I am not going to spend time with that now.

Because there is plenty of testimony and argument to come.

But as you heard Mr. Johnson say, in almost

every respect, in their proposed constructions, University of Pittsburgh wants to take these very narrow claims, particularly the algorithms, and broaden them.

Mr. Johnson cited portions of cases which talk about the broadening of claims.

And in every respect, they want and need to broaden these claims in order to snare Varian in an infringement argument. They can only do it by a vast broadening of their claims.

They have designated Dr. Greenberger as one of their experts.

And as I said, his story is compelling, and he is certainly an expert in his field.

But as we know from Markman and other cases, the testimony of the inventors in a claim construction proceeding is entitled to little deference, and as the case law says is of little consequence in these proceedings.

You heard mention by Mr. Johnson of means plus function elements.

And that is really in large part what is at the heart of the discussion today.

He cited examples.

And there are numerous ones, where the

language says something along the lines of tracking means, tracking movement between successive sets of images and so on.

These are means plus function claims.

And it is very important to go back to the history of what happened with the Supreme Court of the United States and the development of case law in means plus function for just a brief moment.

Back in 1946, the Supreme Court said you can't write -- patent prosecutors can't write claims using means plus function language, because they are attempting to capture every conceivable way to perform a particular function.

To use a simple example, your coffee cup, your Honor, if it is described in a patent claim as a cylindrical object with a bottom and a certain width and a certain structure, to hold coffee with a gripping device to raise it up to your mouth to drink, all of those things define the structure in a way that is sufficient.

But if a prosecutor wants to say simply a means for holding coffee with a means for gripping said means for holding coffee, they are

attempting to capture every conceivable way you could hold coffee, and the Supreme Court said we can't do that.

That is too broad. Those claims are invalid.

So the Congress responded in 1952 by passing the reform act with 35 USC section 12, 112, paragraph 6, which is what is at issue here today, means plus function claims.

So what they have said is means plus function claims are allowed.

But they are only construed to cover the corresponding structure, material or acts described in the specification and equivalence thereof.

In other words, statute allows them but makes them by design very narrow.

They are restricted in scope to the disclosed structure and equivalence.

And if the specification doesn't adequately describe the structure, then they are invalid.

Now, obviously, means plus function found its way in to the description of software and computer inventions as has everything.

In such cases, the courts have held that

the specification must disclose an algorithm that performs the function identified in the claim.

So you will hear a lot today about these algorithms. Algorithms are nothing more than sequence of steps performed by computer software.

So when a patent specification describes an algorithm using flow charts, as you will see both in the patents and in the tutorials here today, there are flow charts in these patents in the specifications.

Those flow charts constitute the structure.

That defines and limits the patented invention.

Notwithstanding the discussion about broadening those, which is the -- what the plaintiffs are encouraging here today.

So the asserted claims we are going to prove and argue today must be limited to these algorithms disclosed in the specifications of these patents.

Pitt would like you to ignore the case law and expand them to cover, as we talked about with the coffee cup, any product that could perform any of these functions stated in the claims.

And we would argue that is improper.

Just to give you a brief overview of what we will do so you know where this is going.

We are going to talk, Matt Poppe, my colleague, will discuss means plus function case law in more detail, particularly as it relates today to computer algorithms.

We are going to call Dr. James Balter as an expert witness.

He is a professor at University of Michigan.

He has specialized in computerized x-ray matching techniques since the 1990's.

He is going to talk about image matching in the '431 patent.

And he is going to give his opinion regarding certain claim terms.

Bill Anthony and Matt will present argument then on the '431.

We are also going to be addressing the '554 patent.

Of course, we have Dr. Steven Jiang here, who began his career as assistant professor at Harvard medical school.

He is now director of research in the department of radiation oncology and a tenured

professor at UC San Diego medical school.

He will testify about the specific algorithms in the '554 patent and the nature of the preexisting technologies for developing detecting patient breathing.

That is really it, your Honor.

That is the overview I wanted to give. I appreciate your time.

Thank you very much.

JUDGE ZIEGLER: All right. You may proceed, counselor.

MR. ANTHONY: My name is Bill Anthony.

I am a patent attorney.

An engineer.

I am not an oncologist, radiation oncologist.

I suppose the world is a safer place for that.

If you permit me, I would like to stand by the board.

JUDGE ZIEGLER: Yes, sir.

You may do that.

MR. ANTHONY: What I will attempt to do is to do this chronologically.

I will take you back in time before the

work of these fellows.
In fact, take you back to a time this whole radiation oncology business started.
And then carry you forward to the point which these claims were allowed or jumping off part of these inventors and the environment in which these claims were allowed.
Because as a case law shows, it is very important that you consider what the environment was at the jumping off point when the inventions -- alleged inventions were made in order to construe the claim.
So that you don't start construing claims in a way that would just cover what was done prior to these inventors.
I would like to acknowledge Dr. Greenberger's excellent presentation.
We agree with much of it. Parts of it, of course, we don't agree with.
That will be up to our witnesses to explain.
Obviously, what I am going to say is not evidence.
And so we will disagree with Dr. Greenberger in part through our witnesses.

There is a term "fiducial" you will hear over and over again.
What helps me understand the term is to think of the term "fiduciary", something trusted.
And a fiducial is a location that is trusted, that can be trusted in the sense it is a very precisely known location in these images. When you see an x-ray that pops out at you and the location is precisely known.
You can trust it as a surrogate for the tumor.
So that when you want to treat a tumor, you can have a fiducial that is a trusted location. This reference point relative to the tumor, so that you can use that to guide your beam, to adjust your beam.
When I think of fiducial, it is not a term I normally use.
In my engineering I don't normally use that term.
But in this case, fiducial is a medical term used in these cases or in these devices, and trusted is what causes me to remember that.
Varian is a very significant company in

this field.
In fact, a leader in this field.
And these linear accelerators that generate these megavolt beams that kill tumors come out of the Varian research that preceded World War II. The klystron tube.
That was invented by the Varian brothers Russell and Sigfurd.
I can skip through some of this quickly.
And Varian after World War II decided as many companies, we have this technology we developed for the war, it is used in radar, let's try to find a good civilian use, something that would be beneficial to mankind.
They decided they would try to use this beam for cancer treatment.
And that was done by Dr. Edward Ginzton, founder of Varian.
The first treatment of cancer using a medical linear accelerator, that is the linear accelerator that causes these megavolt x-rays to be projecteded in to the body, was conducted in 1956 at Stanford University hospital, which is next door to Varian.
We have this young child, a boy of two

years old.
And that is the first patient.
That boy had a brain tumor.
And he was cured through this Varian machine.
That started it all in 1956.
And this gantry that allows you to project the beam through at various angles through the patient, as Dr. Greenberger said to minimize the exposure of good tissue and maximize the exposure of the tumor, was done by Varian in 1961.
I will skip to this is pretty much as described by Dr. Greenberger, where you can enter the body with these beams at various angles.
And by doing that, of course, you are limiting the exposure of good tissue. And next slide.
I am going to show you through this animation how some of that is done.
This is the typical radiation treatment machine.
You have your gantry, patient.
The patient is lying on a couch, which is adjustable in many directions.
And you have at the top of the gantry, you

will have an x-ray source, megavolt x-ray source.
At the bottom an imager. That thing can rotate around the patient.
Now, one of the important aspects is the way in which this beam is formed.
And we see that it is formed through a treatment portal.
This is a doorway through which the beam passes.
And what is significant about that is that that doorway can be changed in configuration.
As Dr. Greenberger said, the tumor is three dimensional, so when you look at it from different directions, it will have a different shape.
And now there is these movable leaves in this doorway.
Here is the doorway.
There is movable leaves.
We can adjust those leaves to configure the doorway to match the shape of the tumor at any particular angle.
And then we project the beam through that doorway in to the patient.

And hit the tumor.
Now, that doorway can be changed.
Normally, this would rotate first, for simplification we haven't done that.
But you see the doorway changes.
So on each rotation, you have a different shape of the three dimensional tumor.
And you will change the doorway.
The portal through which that beam is sent.
That forms the beam.
Now, careful planning is required obviously.
You can think of this like a surgical knife or something that is going to do harm, if you send it in the right place.
And therefore, the physician, a person comparable to Dr. Greenberger, determines the exact location, size and shape of the tumor.
Dr. Greenberger, and this will come out in the testimony, then passes on to a medical physicist, because now you know where the tumor is and what its shape is, now you have to do a lot of engineering to plan the treatment.
And a medical physicist takes over from the oncologist and determines the angle of the

radiation beam.
The dosage from each angle.
Including this intensity and duration and the shape of that portal.
And finally programs the treatment procedure.
Next slide.
Now, often a simulator is used. Not always. Often a simulator is used in order to try out, if you will, the treatment before the treatment occurs.
And the simulator now will send a lower energy, a kilovolt energy beam through the patient among the same directions as the treatment will ultimately be performed.
And so the simulator has some familiar components.
It generates an x-ray beam. This is kilovolt, not megawatt.
Dr. Greenberger said kilovoltage used for treatment.
But I think you will hear from the witnesses, not so in these imaging systems.
And it has the gantry, couch, imager. So it mimics the treatment equipment.

And the simulator, as we said, uses the lower energy, kilovolt beams.
That is very important, your Honor.
It is going to be very important, when you consider the algorithms in this case.
We will match two images.
We are going to match a good image with a bad image.
The kilovolt beam provides a good image.
And additionally, it reduces the harmful effects of radiation.
There is an article in the paper we are having too many CT scans because of excessive radiation.
So using a lower beam energy is significant.
But most importantly, that lower beam energy brings out the features to a much greater extent than the megavolt beam.
So now using the simulation, you position the patient.
You might hear the term "isocenter".
That is the point at which all of the beam -- you send one beam through the patient.
You move the gantry.

Send another beam through the patient.
Move the gantry.
Send another beam through the patient.
That is the point at which all of these beams converge.
That is where the tumor should be.
That is why we are going to use fiducials and other things as we will see later.
Each of those beams is simulated.
And an image.
This high quality image is taken at each treatment position in the simulator.
Next slide.
And every millimeter counts, obviously.
And this Dr. Greenberger touched on.
Let me just say the real problem is when that patient is on the treatment machine, the tumor can't be visualized.
It is typically inside the body.
There is no way for a doctor or a medical physicist to visualize that tumor.
You are working with a dangerous instrumentality.
The megawatt beam is potent. It kills cells.

And the patient may move.
You have to worry about that.
So you have some positioning problems.
One is you have to get the patient in the right position at the start of the treatment.
You need to maintain that proper position during treatment.
We saw these restraints in Dr. Greenberger's presentation.
Those restraints are still used with today's equipment.
That problem has never gone away. I think there was suggestion that the invention somehow avoids those restraints. No, they are still used.
And then you have to detect in response to movement that occurs after you set up the patient on the table. You get the patient in the right position.
And yes, patient is sick, could cough. There could be voluntary, involuntary motions. You have to detect those and respond appropriately.
So let's take the first problem.
Putting the patient in the proper position

in the first instance at start of treatment.
And now I will take you up to the point, the jumping off point with these inventors.
As you might expect, it has been long recognized, remember in 1961 we started moving these gantries around, Varian did, with its equipment.
So it has been known for a long time since at least 1961.
And actually, probably back to 1956 you must accurately position the patient.
And so the issue of matching simulation images and portal images to position the patient has been around for a long time.
At least in the 1980's the notion of using computers to match has been disclosed in prior art.
That was prior art before the patent office examiner.
When this was allowed, examiners said yes, here is a lot of scientists coming up with algorithms for computer matching of these high megavolt range bad portal images and these kilovolt range good simulation images.
So that has been done since the '80s, that

was before the examiner.
There is general principles applied.
You look for things that stand out in both of those images.
That is very important, because the portal image is not a good quality.
You have to determine these -- the location of these features, not only relative to the tumor, but relative to the treatment equipment as well.
And so you have a huge geometric problem, which scientists have been confronting long before these inventors came along and have been using computers to solve that problem.
And by determining these relationships, you determine how the patient should be positioned on the table. You check to make sure the patient is properly positioned.
Now, in the '431 patent, and this now is the image matching patent, the examiner cited three prior art references.
We will discuss these through our witnesses.
So you will have testimony as to what these references say.

Evidence as to what these references say.
One was Young.
We will show you a quick quote from each of these.
And remember the problem here is because portal images are poor.
Because they are done with megavolt x-rays.
And simulation images are good.
If you had two good images, there is no problem.
No one will say there is an invention in matching two good images taken by the same machine.
The problem is two different machines.
Two different quality images.
Taken from different -- in different spacial relationships.
So Young, et al. is trying to solve that problem using computer and discusses an algorithm, that is perfectly appropriate, to match the poor and good images.
Let me bring you back to the kilovolt images.
Two kilovolt images is not the problem.
It is the megavolt image, portal image and

the kilovolt simulation image.
Also before the patent office, in fact, this was a reference that caused the patent to be withdrawn from issuance.
And amended in order to come up with allowable patent.
And that is McParland.
It is very objective to do exactly what we have been talking about.
Have an algorithm, extremely fast and accurate algorithm for registering digital portal and simulation images.
There is your algorithm.
So the examiner is sitting there.
There is algorithms for doing this image matching.
And then Radcliffe is another cited in the patent office before the examiner.
Examiner is presumed to be aware of these.
And certainly there is prosecution history that suggests he is aware of these.
And here, a new image alignment algorithm, pseudocorrelation has been developed.
The algorithm is well suited to the task of automated alignment.

This is exactly the objective of these inventors.
Automated alignment by matching the portal and simulation images.
That was all before the patent office.
That is the jumping off point for claim construction.
Next slide.
So '431 patent is not any algorithm for matching portal and simulation images.
But their particular algorithm. That is how it is claimed.
So if we look at what is in there, let's step through.
There is a lot of hardware, all standard hardware.
I don't think there is any contention this hardware is somehow new and novel.
What is new and novel, obviously, will be standard -- is the algorithms.
The hardware is all old stuff.
I don't think there will be any contention to any other effect.
It is the algorithm.
Now, here we are going to show you how a

simulation image is created.
And then a portal image.
We will show you the problem the algorithms are designed to solve.
Here is the simulator.
This is not the treatment machine. This is the simulator.
We show the patient, we will show some anatomical features including wind pipes and lungs.
There is a tumor right there.
And so we are going to take a simulation image of this patient.
But to do that, we put some trusted locations here.
These x-ray opaque fiducials.
We know when we put those on what their location will be relative to the -- when we put them on, we will determine what their location is relative to the tumor by taking this kilovolt high quality simulation image.
So when we take that image, and we look at the film, or in this case electronic imager, we have those three spots, they pop out at you.
Then there is a tumor, which is hard to

visualize in this.
But in the actual x-ray a professional could see the tumor.
So there is a tumor there.
Now because of that, we have a known relationship between those fiducials, so they serve as a surrogate for the tumor.
This is the treatment machine.
This is the megavolt x-ray image.
It is going through the portal and taking a portal image down here.
This is the portal image being formed down here.
That is a terrible image by comparison. Dr. Greenberger pointed that out.
The fiducials come through strong.
You might see the tumor, because this is a terrible image.
But these fiducials let the equipment know where the tumor is.
Because there is a known relationship you figured out using the simulation image.
These two images are taken in different perspectives, by different machines.
And they need to be corrected.

They need to be rotated one with respect to the other, translated, moved left, right, up and down.
And finally, there may even be need for scaling.
That is these things are not spaced apart the same amount.
You have to move up and down.
Expand one image relative to the other to bring it to the same scale.
And our experts will talk about the algorithms in the patent for doing that.
And those motions can be accommodated. Those differences in the images can be accommodated by correspondingly moving the patient. You can rotate the patient as the patient is on the bed.
The platform.
You can translate the patient, move it to the side.
Forward.
Head forward.
And you can also adjust the height of that bed, that platform, so that you can adjust the scale.

So it is those effects, translation, rotation scales, skew, deformation, that these algorithms are trying to accommodate.
And that is very, very clear, that this patent is directed to solving that problem.
It has algorithms for solving the problem of those image mismatch factors.
And one key thing in this algorithm in distinguishing -- this is the file history.
This is an argument being made by the applicant's lawyer to the patent office examiner to get the patent allowed.
And they are dealing with McParland, which had an algorithm for matching portal images and simulation images.
And he says, "Yes, but our algorithm is better.
"Our algorithm doesn't require the input of identification or information in the images such as the anatomical match points required by McParland. So our algorithm is better."
So today we will look at what is this algorithm through our witnesses.
Our witnesses will testify. What is the algorithm that does that?

That is what this patent is directed to.
And part of knowing -- you can match a portal image with a simulation image for patient positioning.
You can also match two portal images.
You already have the patient properly positioned in the equipment, in the treatment machine.
Now you can match successive portal images and track patient movement.
So you can watch the patient.
It is like taking an x-ray video, so instead of seeing an image of a person moving across the room or something like that, this is an x-ray video, where you can see the skeleton or the x-ray image of the patient, the patient moving through those.
That is done by instead of comparing a -- the portal image with the earlier taken simulation image, you compare successive portal images.
That is one other feature in the second feature of the '431 patent.
Next slide.
Now, before you can do this algorithm, as

we have shown in the earlier step, you have to place fiducials on the patient's body.

And so that is the starting point, the trusted reference points that will allow you, even though you are working with a terrible image in the end, the portal image, you still know where that tumor is, because you have surrogates.

So you place those x-ray fiducials on the body.

And they are going to show up in the same place.

You want to, in order to align these two images after you have the -- the portal and the simulation image, you are going to use those to line the images by steps, which will include placing, modifying one image, so that the two images of the fiducials are about the same.

And there is nothing in the '431 patent how you match portal and simulation images other than using fiducials.

It is all about the fiducials.

And there is three basic steps.

Our witnesses will take you through these in some detail.

Coarse alignment.

And then prepare for fine alignment.

And finally fine alignment.

That is in the algorithm that accomplishes this goal set forth in the '431 patent that purportedly distinguishes the prior art.

Let's go on to the next.

And after do you these three steps, which will be described by our witnesses, the images can be displayed, the physician can look at them.

Or medical physicist can look at them.

Or you can use them for tracking by looking at successive portal images.

And this is the specific algorithm. Our expert will take care of that.

The second problem is after you get the patient all aligned on the treatment machine, what if the patient moves and we have to accommodate that?

There is two types of movement. One is sudden movement, cough, patient voluntarily, involuntarily moves, such as sit up.

And periodic movement, which is somewhat predictable, such as breathing or heart beats.

And '431 patent says it is matching algorithms can be used to address patient

movement.

And that is that second feature of the '431 patent, which is taking a rapid series of successive portal images to provide this x-ray video so can you watch it. It looks like watching a TV.

But it is the skeletal image you see.

Now, this process is called tracking.

So when you do successive portal images, and you do it quickly enough, you can watch this movement, you can track.

Tracking of course means that you pay attention to -- you do something to track.

You can't be just measuring it.

You have to do something to track.

Let's get to the second patent, which is periodic patient movement.

This is the '554 patent.

That is movement during treatment.

And we are going to illustrate that problem.

I think Dr. Greenberger illustrated it as well.

This is a different way to show it.

Here is the tumor.

The patient is breathing in and out.

And his chest is expanding and contracting.

And since this is a tumor on the lung, and the lung is inflating and deflating, that tumor is moving around.

And that is the problem.

How do you make sure you treat just the tumor and not the good tissue?

And this is the surrogates.

We are going to put these fiducials, so we know where that tumor is relative to the fiducials.

Now we can watch the fiducials move.

We know a relationship between movement of the fiducials and movement of the tumor, and we can act quickly and accurately based on that relationship.

That relationship we figure out and send the signal to turn the radiation beam on or off.

Or to warn.

So now in 1954, so I am going now to the jumping off point for the second patent.

As I discussed earlier, there was a jumping off point for the first patent, the image matching patent where a number of scientists had

come up with image matching algorithms.
And now we are going to the jumping off point for the second patent.
This is the movement, accommodating movement.
Once again, this was a known issue.
And a number of scientists had proposed solutions.
Including using light type fiducials to paint a light picture on a patient with laser.
And that would become the surrogate.
A video camera would look at the light images painted on the body of the patient by the laser.
And would sense the movement of the lights relative to the body.
And then send signals to the x-ray equipment, the linear accelerator to turn it off, whenever the tumor moved outside the beam.
So that concept, almost not quite a decade before the inventors.
These were, I think Mr. Johnson said, what we are doing is looking at the patient to detect this movement and respond to it.
And these all look at the patient to detect

this movement and respond to it.
And so here is another one, the Beroni article, just prior to the work of these inventors.
Here they have two kinds of fiducials.
They have a fiducial similar to the earlier reference, which is an image, light image painted on the body by a laser.
But also it allows the use of artificial fiducials.
These x-ray -- not x-ray opaque but things that would show up to a camera.
So you see in the image from that article, both types of fiducials, the artificials which are on the skin. On the patient.
And the video camera. And say we can use either of those or both of those.
Two video cameras look at it, capture movement.
And then the software would process that.
And then use that to turn the x-ray beam off, whenever the tumor got outside the beam.
So another piece of prior art.
So these were known ways of doing this to measure the movement of the patient, turn off the

beam.
And one was to measure the volume of the chest using a strain gauge, put something across the chest, that when the chest expanded, it would expand the strap.
When the strap expanded, it says okay, you are inhaling.
When it contracted, you are exhaling. And would use that to measure movement of the body.
Also in the prior art things for measuring air flow through the patient's mouth, because that was an indicator of breathing.
That is actually a pretty decent process, that as University of Pitt found out. The technical term is spirometer.
Finally, you measure breathing also by putting an electronic or electrical temperature gauge and measure the hot air coming out of the patient's chest.
So that is all -- some of the jumping off point.
So now just as the '431 patent said, this stuff has all gone on before, but we have something new.
It is a new algorithm.

And once again, in the claims, there is a whole bunch of hardware.
And no one is going to argue, I don't believe, that any of this hardware is particularly novel, computers, keyboard, CCD cameras.
What is the essence of this patent, what is described in detail, just like in the '431 patent is the algorithm.
The algorithm that supposedly performs this result.
That algorithm will be explained by our experts.
The '554 patent says this algorithm is superior to the prior art.
Because it detects and tracks movement under varying light conditions.
One of the things they are trying to do here is use ambient light, which gets brighter or darker depending on people that move in front of lights.
The gantry moving back and forth in front of lights.
They said we don't need a special light source.

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We have an algorithm that will accommodate these variations in light sources. Or the ambient light.
And their algorithm improves speed of fiducial tracking.
If you will do this, you better be right.
You better be accurate in timing when to turn that beam off.
So you need to have a high speed tracking.
And they said their algorithm does that.
And enables tracking with as few as one camera and one fiducial.
These are all of the claims this patent made to convince the examiner their algorithm was better than the prior art.
And finally, generates gating signals, first provides a warning.
Sort of like a yellow light and a stop light system.
Then of course, once you get too far, it turns off the beam.
It is a red light.
And there is the statement, column 2, lines 4 and 8 of that particular effect of their algorithm.

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And that is it, your Honor.
Thank you for your attention.
JUDGE ZIEGLER: Thank you, Mr. Anthony.
MR. JOHNSON: You just heard this patent is all about an algorithm.
I am going to address what I consider to be the argument and the comments in the opening later.
My client is effectively called a troll.
We will deal with that in our closing.
But I would like to at this point focus on what we are here today to determine.
And that is what these claims mean based upon what is stated in the patent.
So if we will, let's look at the '554.
Because we don't have to guess what this patent is about.
We are told.
If you look at the abstract.
Right at the outset, it makes it clear that -- it talks about a camera generates digital image signals representing an image of one or more natural or artificial fiducials on a patient positioned on treatment or diagnosis equipment.
The reason that is important, is you are

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going to be asked to construe what is a camera.
You are being asked to construe what are natural or artificial fiducials.
And those are the claims -- the terms that the other side said needed interpretation.
And in the abstract, it talks about a camera.
And one of the arguments we are making is a camera is well known and understood.
The other side makes arguments about what are or are not fiducials.
And as you can see, both natural and artificial fiducials are disclosed as part of the patent.
Now, you just heard that this patent is all about an algorithm.
If you will, I would like you to take a look at column 1.
Column 1 defines -- gives you a clear description of what the patent covers.
And what it says, if you go down to lines 29 through 47, it says, "In addition to patient movement, which would cause the tight beam to miss the tumor, it is important to be able to detect patient movement, which could cause a

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collision between the patient and the linear accelerator, which is repeatedly repositioned to establish the multiple treatment beams."
In other words, detection is important.
And then they describe exactly what it is they are trying to get from the patent office.
And they say there is a need therefore for an apparatus.
An apparatus is not an algorithm.
"For detecting patient movement on radiological treatment and diagnostic equipment, there is a particular need for such apparatus, which can detect submillimeter patient movement in real-time.
"There is also a need for such apparatus, which can detect patient movement initiated from various treatment positions.
"There is also a need for such apparatus, which can detect patient movement under varying lighting conditions.
"There is a further need for such apparatus which can discriminate movement associated with patient breathing from other movement and accommodate therefore."
That is what they were seeking from the

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patent office.

And the prior art that was cited did not encompass what was being sought in this patent issue.

In the summary of invention, it says, "These needs and others are satisfied by the invention which is directed to apparatus responsive to movement of a patient which identifies and tracks movement of at least one passive fiducial on the patient."

It gives you a general description of what the patent says.

Not what the argument is.

If you look over on column 2, scroll down to about line 12.

It says, "As yet another aspect of the invention, the means determining movement of the passive fiducials includes means detecting movement associated with patient breathing and random movement.

"The movement associated with patient breathing can be used to generate a gating signal synchronized to patient breathing.

"This gating signal can then be used to actuate the beam generator only during selected

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parts of the breathing cycle."

This is what the inventors thought that they were inventing, what the patent office thought it was allowing.

And what we are going to do is demonstrate to you that following the law, as you must, and looking at what is claimed in the specification, what is written, that the terms that we define, as we define them, are proper and appropriate.

At this time, I would like to have -- I would like to turn it over to my partner, to enable him to proceed with Dr. Schell, who will discuss for you the issues you need to decide.

One, what constitutes the standard of one of ordinary skill in the art, in connection with this patent.

And two, how would one understand those claims to be construed.

That is different from arguing about other issues concerning how the patent works, which is not before you at this time.

MR. ZELE: I just want to follow up with what Dan was saying.

There were terms I saw in some slides that talked about the patent claims something.

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If you look carefully at the parts of their quoting, those parts aren't in the claims.

That is not what is being claimed in the patent.

The claims are at the end of the patent.

The quotes are taken willy nilly from throughout the patent specification.

So that is not what is being claimed.

Dr. Schell, are you ready?

JUDGE ZIEGLER: Do you want witnesses sworn?

MR. ANTHONY: Yes.

(Witnesses sworn.)

JUDGE ZIEGLER: Your name, sir.

THE WITNESS: Michael Schell.

MICHAEL SCHELL

Called as a witness by the plaintiff, having been first duly sworn, was examined and testified as follows:

DIRECT EXAMINATION

BY MR. ZELE:

Q Dr. Schell, would you introduce yourself?

A I am the director of medical physics at University of Rochester.

I have been in that position for 16 years.

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My educational experience is bachelor's degree at State University of New York at Stonybrook.

Subsequent to the bachelor's degree, I was conscripted in to the army.

I served at Walter Reid Army Institute of Research in a radio protective drug screen program.

After that, I matriculated at the University of Kentucky.

Took the core courses for Ph.D. in nuclear physics.

And performed a fast neutron scattering experiment off of some rare earth isotopes.

I elected to move on, because there weren't positions in nuclear physics.

Q Could you tell me what you do at University of Rochester?

A I have three functions that most medical physicists do.

That is patient care.

Teaching.

And research.

I have been involved with introducing new techniques, including stereotactic radio surgery with the brain and the body.

I also administer the group to make sure

things are running smoothly and are faced with entities like the state of New York, when they audit us or JACO.

Q Do you work with equipment, radiation therapy equipment on a daily basis?

A Yes.

I assist with taking care of the quality assurance of linear accelerators, which are all made by Varian.

And we have electronic portal imagers on a subset of the system.

The system has seven Linax right now.

Q Are you a member of any professional associations?

A I belong to American Association of Physicists and Medicine.

The American College of Medical Physics.

And ASTRO.

And American College of Radiology.

I was elected to fellow membership in the AAPM several years back.

And a fellow member of the American College of Medical Physics last May.

Q What does it mean to be a fellow of these organizations?

A It is generally a recognition of past achievements and contributions to the field.

Q Do you have any certifications?

A I am board certified by American Board of Radiology, 1980.

Q Have you any publications?

A I have on the order of about 69 refereed publications in the literature.

Some book chapters among other things.

Q We would like to move to admit Dr. Schell --

JUDGE ZIEGLER: Any questions?

MR. ANTHONY: Yes, your Honor.

I will skip voir dire -- no. Let me voir dire, your Honor.

CROSS EXAMINATION EN VOIR DIRE

BY MR. ANTHONY:

Q Dr. Schell, my name is Bill Anthony.

I am an attorney representing Varian. We haven't met before.

But good morning to you, sir.

A Good morning.

Q Let me ask you just a few things on your background.

You don't recall whether you have written a

computer program in the last ten years, sir?

A True.

Q And you have not written any software for imaging applications?

A That's true.

Q And you have never attempted to write a commercial software application any of kind?

A True.

Q And you don't know which programming languages are typically used by persons of ordinary skill in the art in 1996?

A Well, in that era, it could have been C or FORTRAN, among other languages.

Q You are not a C programmer?

A No.

I am not.

Q You don't know whether they used FORTRAN at that time?

A Well, who is they?

Q A person of ordinary skill in the art in 1996.

A Well, I used FORTRAN myself.

But for other purposes.

Not for image analysis.

MR. ANTHONY: No further questions.

JUDGE ZIEGLER: All right.

Your motion is granted, sir. You may proceed.

DIRECT EXAMINATION (Resumed.)

BY MR. ZELE:

Q Dr. Schell, did you review the '554 patent?

A Yes, I did.

Q Did you form an opinion as to the level of ordinary skill in the art with respect to '554 patent?

A My view is that ordinary skill of the art would be MS medical physicist with about five years experience, or radiation oncologist with the assistance of a software programmer.

Q Did you review the '431 patent and its prosecution history?

A Yes.

Q Did you form an opinion as to the level of one with ordinary skill in the art --

A A Ph.D., medical physicist with five years experience, or a radiation oncologist with a programmer with a master's degree.

Q With respect to the '554 patent, did you form an opinion as to the meaning of the term "camera" in claim 20?

A My view is the camera is simply a device,

which captures the image of the patient.
It is not in a means plus function format.
Q Why do you believe it is not a means plus function format?
MR. ANTHONY: Objection. Requires legal conclusion.
JUDGE ZIEGLER: Overruled.
You may answer.
Q Question is: Why do you believe the camera is not a means plus function format?
A The camera is simply a physical device to acquire the images. Not part of any innovative process or algorithm.
It is readily available at the time of the patent.
Q In 1996, did people know how to buy cameras?
A Probably from 1980 when George Eastman developed a portable film camera.
Q In connection with the '554 patent, is the term camera limited in any sense to a particular portion of the spectrum?
A No.
Past use of the cameras was either invisible spectrum or the infrared.

Q Could you give examples?
A Well, the example that I have been using for since 2000, but it was invented in the late 1990's, is brain lab radio surgery system for body radio surgery.
Which is looking at radio-opaque fiducials that are placed on the patient, but in the patient setup stereotactic localization is illuminated with infrared light.
The infrared light is filtered to reduce noise of the background.
Q Was there anything in that '554 patent prosecution history that caused you to believe that the camera is not limited to a particular part of the spectrum?
A Well, there is evidence in the patent history of previous patents using cameras with infrared light and visible.
MR. SNEATH: Could you keep your voice up? I am having a hard time hearing.
THE WITNESS: I am sorry.
MR. SNEATH: Remember. He is taking it all down.
Q With respect to the '554 patent, did you form an opinion as to the meaning of the term

"digitizer"?
A A digitizer is a device that acquires, transforms an analog image in to a digital format that can be used by computer software.
Q Could you give me examples of digitizers used in 1996?
A Well, in the '70s, digitizers not in this context were used to hand digitize patient contours in to treatment planning computers.
At the time of the patent, there were film digitizers, whether they are laser digitizers or using visible light to digitize radiographs in to a digital format.
There is also frame grabbers you can purchase to interface with a camera to convert the output of the camera in to a digital format.
Q In 1996, were people able to buy digitizers?
A It was an easily -- Vidar scanners were available. Matrox frame grabbers were easily available.
Nothing unusual.
Q Were those known to one with ordinary skill in the art?
A Yes.

Q Further, with respect to the '554 patent, did you form an opinion as to the meaning of the term "fiducial"?
A Well, fiducial is simply a marker. Pure and simple.
Q What does it do?
A It is an identification point that one can use either on a patient or any image that allows you to track or identify the position of the object in 3D space.
Q And claim 21 of the '554 patent uses the phrase "at least one fiducial on the patient".
Did you form an opinion as to the meaning of that term?
A Well, it is possible within the patent designed to use one fiducial marker or an array of markers.
There is no difficulty.
Q Does there have to be any -- does '554 patent require any special relationship between fiducials?
A No.
The patent allows for either rigid relationship between the fiducial markers, if there is more than one.

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Or it allows the markers to be flex in space.
There is no restriction.
Q Let's then turn to the '431 patent.
Did you form an opinion as to the meaning of the term "digitizer" in the '431 patent?
A Well, the '431 patent delineates the use of digitizers on different devices.
So there is more than one digitizer required.
Q Could you explain that?
A Do we have a laser pointer?
Q If it is all right with the judge, maybe you can point.
JUDGE ZIEGLER: Surely.
A In the context of the patent, this is the simulator.
And the simulator can have either a film plate, a cassette. Simulators also come with image intensifiers.
Modern simulators can have an electronic portal imager.
So if you are using the film on the simulator, you would have to develop the film and scan it in with a film digitizer.

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If you are using an image intensifier, the output would go through a different type of digitizer on the treatment Linac.
If you are using electronic portal imager, output goes through a digitizer within the EPI device itself.
So there is different types of digitizers involved.
Q Does the -- your understanding of the '431 patent, is it limited to a single digitizer?
A It can't be.
Q Why is that?
A Because the two devices are different.
You can't have function in a department, simple necessity, if you are limited to one digitizer and images are flowing off the units at the same time.
Q Is your belief based on the description in the '431 patent?
A Yes.
Q Continue on the '431 patent.
The term "successive".
Did you form an opinion as to the meaning of the term?
A Well, successive, within the context of the patent can mean either successive images following one

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another in time. Within a given beam treatment.
Or it can actually mean successive images between fractions.
So that you could look at digitized images from fractions 1, 2, 3 on to 20 or the end of the treatment.
Q In your opinion, was there a special definition of successive in the '431 patent?
A Successive just means following one another.
Q Let's go back to digitizing.
Did you form an opinion as to the word "digitizing" in claim 21 of the '431 patent?
A Well, digitizing simply means converting from an analog format to a digital format.
That is all.
Q Is the same true in claim 26?
A True.
Q Did you form an opinion as to the meaning of the word "x-ray image" in the '431 patent?
A Well, x-ray image is simply an x-ray beam will pass through an object, if the object is not homogenous, the heterogeneities in the object will modify or modulate and attenuate the x-ray beam.
But the pattern of an x-ray beam coming out

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from the backside of the object will have a modulated effluence.
Any detector that sees that effluence will produce an image that reflects the differences in the photon intensity across the 2D image.
Q In your opinion, is the term "x-ray image" as used in the '431 patent limited to a particular type of x-ray image?
A X-ray image could be -- within radiation therapy could be the simulator image.
It could be the portal image. It could be -- and it can vary in energy.
It is not limited.
Q Did you form an opinion as to the meaning of the term "reference image" in claim 26 of the '431 patent?
A Reference image simply means the image that the other images are referred back to.
Q Is the term "reference image" in the '431 patent limited to a particular type of image?
MR. ANTHONY: It is leading, your Honor.
Perhaps we can have the witness's testimony.
JUDGE ZIEGLER: Overruled.
A Reference image back in the time of the patent usually would refer to a simulator image.

But it also is not limited.
It could be an image outside of the simulator.
It could be that there is a reference image generated by setting up the patient on the linear accelerator.
In effect, using the simulator -- the Linac as a simulator.
But there is no limitation on reference image.
Q In 1996, were there other types of reference images known in the radiotherapy field?
A Well, at the time of the evolution of 3D planning, one can generate a digital reconstructed radiograph of a treatment beam in the treatment geometry. And one could use that as a reference image as an example.
Q Are there any others?
A Well, now one can use a CT simulator to generate a reference image.
Q And in connection with the '431 patent, claim 21, did you form an opinion as to the meaning of the term "portal image"?
A Within the confines of the patent itself, portal image is the image of the patient in the

treatment geometry.
That is basic -- it is not restricted.
Q In your understanding of the '431 patent, is the term "portal image" limited to a particular energy range?
A No.
Portal images can be acquired -- for example, if one is treating with a very high megavoltage beam, say 16MV, you can acquire a portal image with the six MV beam on the linear accelerator and get greater soft tissue discrimination.
One could attach a kilovoltage x-ray tube on the side of the gantry as had been done back in those days and acquire a portal image by rotating the gantry to bring the KV tube in line with the treatment geometry and get a portal image with a low energy x-ray.
Q What does a portal image do?
A A portal image actually gives you the image of the patient in the treatment geometry.
In other words, from the view of the source of the x-rays passing through the patient you have geometry of the patient relative to the geometry of the treatment machine.
Q No further questions.

JUDGE ZIEGLER: We are going to take a ten minute recess, Mr. Anthony.
Then we will come back and continue for your examination, if any.
(Recess taken.)
JUDGE ZIEGLER: I think we are moving to Mr. Anthony's cross examination.

CROSS EXAMINATION

BY MR. ANTHONY:
Q Good morning, again, Doctor.
A Good morning.
Q The '554 patent, that is the patent in which we track patient movement during breathing, for example; is that correct?
A Yes, sir.
Q And that patent shows in claims camera means; is that correct?
A Beg your pardon?
Q Camera means is associated with the '554 patent; is that correct?
A Yes, sir.
Q And that is the camera that is looking at the patient and looking at fiducials so that you can turn the beam off at the appropriate time; is that correct?

A Yes, sir.
Q And that requires pretty fast response?
A Yes, sir.
Q And did I understand that you said that camera could be a film camera?
A No.
Q It can't be a film camera?
A No.
Q You made reference, when asked what a camera means was, you made reference going all the way back to when Eastman Kodak discovered film, I believe it was.
A Well, that is camera in general.
Q I see.
So a camera in general is not the camera of the '554 patent?
A Not for looking at the fiducial markers, no, sir.
Q And as of the filing date of that patent in September -- September 19th, 1996, did you identify for us particular cameras that people reading the specification would understand that camera to be?
A You mean did I look for commercial examples?
Q Or did you tell us as part of your

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testimony this camera will work, and therefore it is part of the camera means of the '554 patent?
A I did not identify any particular camera.
Q And you didn't see an identification of any particular camera in the '554 patent; is that correct?
A Just that it was a CCD type camera.
Q But that is a broad category; is that correct?
A Yes, sir.
Q And some of the cameras that fall in that category would be satisfactory.
Is that correct?
A Yes.
Q And some would be unsatisfactory?
A Sure.
Q And you run experiments to determine which ones performed adequately and which ones did not.
Is that correct?
A Yes, sir.
Q Now, let me turn to the '431 patent.
That is the patent where we matched two images, a portal image and a simulation image.
A Yes, sir.
Q And in that case, you told us about the digitizer of that patent.

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It is element 29, figure 1.
He is going to put it on the screen.
You can look at your own patent as well, sir.
Why don't you look to your own patent, figure 1.
There it is.
So it is item 29 is the digitizer?
A Yes, sir.
Q Did I understand your testimony, sir, that that digitizer can be two different things?
A Well, it all depends what is detecting the x-ray image.
With respect to the patent, the simulator on the left could have a film.
And a film cassette.
If you are going to use that as a reference image, you would have to develop the film and scan it in to a scanner, then digitize the image that way.
If it is a electronic portal imager, the imager provides a -- has a digitizer within it.
And then moves the image off to the computer system.
If it is a portal imager based on a scintillation screen with a reflecting mirror and a

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regular CCD camera, you would grab the image that way.
And you would need a different type of digitizer for the image in digital format.
Q Did you see any specific structure disclosed in this patent for any of those digitizers?
I am referring to the '431 patent.
A You mean any particular device identified?
Q The structure of any of those digitizers.
A I don't recall any particular structure.
Q Now, sir, moving on to portal image, did you -- when we talk about portal image, now we are talking about the '431 patent, the matching of two images, portal and simulation, sir.
A Yes, sir.
Q And you would agree that portal images that are typically megavolt images?
A It is very common they are megavolt images.
Q And sir, these megavolt images have lower quality or resolution than the typical simulation image done at kilovolt power?
A Well, to be specific, they will have lower contrast.
Because the photon interaction is the Compton scattering.
It gives you less contrast in the image.

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Q When the term "portal image" is used, it is your understanding the portal image is an image of the treatment port.
Is that correct?
A It is an image in the geometry of the treatment port.
My first position as a medical physicist was in neutron therapy facility.
And it was very difficult to get a reasonable contrast image with a neutron beam.
So we would move the patient in to the geometry of the port.
But use a KV x-ray generator and regular film with markers outlining the port on the patient.
To mimic the treatment of the patient.
Q Your Honor, move to strike.
That really wasn't the question, what he had done at some point in the past.
JUDGE ZIEGLER: Sustained.
Q Now, sir, a portal image should have the same shape as treatment beam.
Is that correct?
A Yes, sir.
Q The beam that generates portal image should mimic the treatment beam?

A The shape of it.
Q Yes.
A Yes.
Q And so should have the same gantry angle, table angle and collimator angle as the treatment beam?
A Yes, sir.
Q If the image, the portal image is not taken from the same angle as the treatment beam, it would not be useful image?
A If one had a KV tube on the side of the gantry, you can rotate that tube in to the position of the x-ray beam that would be treated with, and you could obtain a higher contrast image of the treatment beam itself.
And that we can regard as a portal image.
Q Move to strike, your Honor.
Nonresponsive.
JUDGE ZIEGLER: Overruled.
Q Let me ask the question.
Listen to it very carefully.
If the image is not taken from the same angle as the treatment beam, then it would not be a useful image?
A I don't believe that to be the case.

Haynes radiation therapy tube.
Q Sir, do you recall being asked that question during your deposition?
A Yes, sir.
Q Sir, I will show you your testimony at page 92.
Line 10.
Through page 93, line 2.
Would you read that testimony to yourself, please?
A Where are we?
Q Page 92, line 10.
Through page 93, line 2.
Read that to yourself, please.
A "If in that system" --
Q To yourself, sir.
A Go ahead.
Q Is it fair to say that the portal image, you must take the image at the same angle that represents the beam direction you treat with. Otherwise, it would not be a useful image?
A And my response is that if the KV tube is in the same direction as the megavoltage beam, then you would have a higher contrast image and use that as a portal image.

Q Now, point to the '431 patent, sir, where disclosure of that KV tube that rotates in that position --
A It is not in there.
Q It is not in there.
A No.
Q Thank you, sir.
A It doesn't exclude it either.
Q That is okay, sir.
That finishes my cross.
JUDGE ZIEGLER: All right, sir.
Counselor.

REDIRECT EXAMINATION

BY MR. ZELE:
Q Does the '431 patent exclude the use of a KV?
A No.
It does not.
Q Is there any particular part in the patent you could recall that describes the required power?
A No.
I don't recall.
You mean required energy.
Q Required energy.
A No.

I don't recall.
Q Is there one?
A No.
Q Counsel asked you if -- counsel asked you if there was a particular structure disclosed in the '431 patent that performs the digitizing.
My question is slightly different.
Does the '431 patent disclose a structure that performs digitizing?
A Well, it is in line 29.
Q What is that structure?
A A digitizer.
Q Would that digitizer be different types of digitizers?
A Well, within the framework of figure 1, it would have to be, because you -- it is conceivable, again, that you would have a film image to digitize from the simulator.
Or you could have an image intensifier tube image that you would have to digitize.
Those are different digitizers that would be required as opposed to the digitizer built in to an electronic portal imager.
So they are necessarily different digitizers.

Q Would that be the understanding of one with ordinary skill in the art when the application was filed?
A Yes. It would have been.
JUDGE ZIEGLER: Anything further of this witness?
MR. ZELE: No.
JUDGE ZIEGLER: Mr. Anthony?
MR. ANTHONY: No, your Honor.
JUDGE ZIEGLER: Mr. Johnson, call your next witness.
MR. JOHNSON: We have no further witnesses.
We are ready to argue.
JUDGE ZIEGLER: Plaintiff has presented its case.
Varian has the opportunity -- you want to present oral argument as part of the presentation of your own case?
MR. JOHNSON: I can do it now or I can wait.
JUDGE ZIEGLER: I would prefer we wait.
MR. JOHNSON: Good.
JUDGE ZIEGLER: Is Varian ready to proceed?
MR. ANTHONY: Yes.

We are.
JUDGE ZIEGLER: Mr. Anthony.
MR. ANTHONY: Actually --
MR. SNEATH: I will swap chairs.
MR. POPPE: Varian would like to call Dr. James Balter as our first witness.
MR. ANTHONY: I don't know if I presented Mr. Poppe before.
This is Mr. Matt Poppe, a partner at Orrick.
JUDGE ZIEGLER: Mr. Poppe, how are you, sir?
MR. POPPE: Very well. Thank you.
How are you?
JUDGE ZIEGLER: Dr. Balter, come forward and raise your right hand.
DR. JAMES BALTER
called as a witness by the defendant, having been first duly sworn, as hereinafter certified, was examined and testified as follows:
JUDGE ZIEGLER: State your full name.
THE WITNESS: James Michael Balter.
JUDGE ZIEGLER: How do you spell the last name?
THE WITNESS: B-A-L-T-E-R.

JUDGE ZIEGLER: Mr. Poppe.
DIRECT EXAMINATION
BY MR. POPPE:
Q Dr. Balter, where are you employed?
A At University of Michigan.
Q What is your position there?
A I am an associate professor in radiation oncology.
Q How long have you been at University of Michigan?
A For the past 15 years.
Q Would you please describe your graduate education?
A Certainly.
I have a Ph.D. in medical physics through the radiation oncology department at University of Chicago, which was granted in 1992.
Q Could you describe, please, what medical physics refers to?
A Sure.
Medical physics is the general practice of principles primarily understood by physicists to the safe application of medicine.
In this case radiation oncology.
Q And how did medical physics apply to the

area of radiation oncology?
A Radiation oncology is essentially clinical use of radiation both administered locally by brachytherapy and at a distance by teletherapy as described earlier this morning.
To do so, we need to control the amount of radiation, the way in which it is delivered.
And we need to understand how to model that radiation transport, so we can accurately deliver multitreatment beams previously described and safely operate the equipment necessary to handle the radiation delivery.
Q I will ask if you could just slow down a little bit.
A Certainly.
Q Thank you.
Do you have any particular research specialty?
A Yes.
I do.
Q Could you describe that, please?
A My research focuses on the areas of patient positioning.
Organ motion.
Patient modeling.

And imaging systems.

Q Do any of those research specialties, that you have described, relate in any way to the '431 patent?

A Yes.

They do.

Q Would you please describe that?

A The '431 patent deals with the general area of using image matching or registration techniques to aid in patient positioning and tracking and radio therapy.

This was the major focus of my doctoral dissertation and significant focus of my research since then.

Q How long has that been your research focus?

A I would say I started looking at image matching problem in roughly 1989.

Q Do you have any computer programming experience in connection with radiation therapy?

A Yes.

I do.

Q Please describe that?

A Prior to my doctoral dissertation, I worked both for universities and medical imaging companies doing computer programming, imaging applications.

During my doctoral dissertation I wrote code for image registration and image enhancement.

Subsequent to my doctoral dissertation, I have written numerous programs for image registration, collaborated image registration experiments with other programmers.

And developed computer control code for image registration and machine control.

Q I will hand you a document and ask if you could please identify it for the record.

If you could identify the correct exhibit for the record, please?

A Yes.

This is a copy of my curriculum vitae, CV.

Q Is this a true and accurate copy and up to date as of the present date?

A It is an accurate copy and is reasonably up to date.

Q I move Dr. Balter's CV in to evidence.

JUDGE ZIEGLER: Any objection?

MR. JOHNSON: None.

JUDGE ZIEGLER: Admitted.

MR. POPPE: I would move to have Dr. Balter qualified as an expert on the subjects of portal imaging and x-ray image matching.

JUDGE ZIEGLER: Any questions?

MR. JOHNSON: No. For purpose of this hearing I stipulate.

JUDGE ZIEGLER: Motion granted.

BY MR. POPPE:

Q Do you have in front of you a copy of the '431 patent?

A Yes.

I do.

MR. POPPE: Your Honor, would you like a courtesy copy?

JUDGE ZIEGLER: Why don't you give us an extra?

Q Dr. Balter, you have been handed a copy of the '431 patent.

Have you seen this patent before?

A Yes.

I have.

Q Have you reviewed it?

A Yes.

I have.

Q Have you formed an opinion regarding the level of education and experience that a person of ordinary skill in the art this patent would have?

A I believe I have.

Q Would you describe that opinion, please?

A This patent deals with two technical concepts. That is the precision delivery of radiation and the use of computer base image registration methods.

So a person of ordinary skill in the art at time of this patent would have to have skills that would understand both of these.

Q What level of skill?

A You can imagine two types of person.

One would be, for example, a medical physicist with some exposure to image processing and/or computer programming techniques.

The other type of person would be actually the opposite, a computer programming person, who is working for either a radiation oncology department, developing image processing techniques, or working for a company that is involved in developing portal imaging systems.

Q I will direct your attention to the screen.

We pulled up claim 21 from the patent.

Have you reviewed this claim before?

A Yes.

I have.

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Q And I will refer you to four lines down,
where it refers to a means digitizing successive
portal images to generate successive sets of digital
portal image signals.

Now, we have asked you to identify the
structure in the patent specification that corresponds
to that digitizing means.

Is that right?

A That's correct.

Q Have you done that?

A Yes.

I have.

Q What did you conclude about the
corresponding structure for the digitizing means?

A Well, I could find two references to a
digitizer. That as already described block 29 of
figure 1.

And also a sentence found in column 4 of
the patent.

And basically, there is no specific
structure identified.

Q Why do you say that?

A All it shows is a box called digitizer on
the graph, and all the digitizer says in column 4, if
it is okay for me to quote from the patent

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application.

JUDGE ZIEGLER: Of course.

A Is that the image matching system includes
the digitizer, which digitizes a simulation image such
as produced on the x-ray film, and the portal image
such as that generated by the electron portal imager.

Q Why is it your opinion those references to
digitizer do not specify a specific structure?

A Well, the problem is that there are many
forms of digitizers available at the time -- of
digitization available at the time.

And the method of digitization would
dramatically influence the utility of the resulting
images that came from it.

Q Would you please describe the types of
digitizers available in 1996, that you are referring
to?

A Certainly.

There were methods of digitizing films,
which included mechanical optical scanners.

Laser film scanners.

And cameras connected to analog to digital
converters.

There were digital imaging systems, such as
early portal imaging systems, which either had a

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camera and a mirror, and different types of cameras
with different imaging characteristics.

There was the liquid ion changing imager,
which had crossing of high voltage wires, and the
digital signals would in fact be the electrons
collected at these crossings of wires.

Q And does the '431 patent refer anywhere to
any of those particular structures, that you just
described?

A I couldn't find any reference to any of
those structures.

Q Would all of those structures for
digitizing that you described be equally useful for
purposes of the '431 patent?

A No.

They would not.

Q Why do you say that?

A Because the different methods of
digitization had different speeds.

Different spatial resolutions.

Different inherent contrasts.

And they actually had artifacts and
distortion.

And each of these characteristics would
affect the utility of the resulting images.

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Q In your opinion, would all those digitizing
mechanisms work in the context of all of the claims --
or of claims 21 and 26 of the '431 patent?

A I don't believe so.

Q Why is that?

A For example, the liquid ion chamber
digitizer required high level radiation dose and a lot
of time to make an image.

To do so would actually mean that part of
the treatment would be in fact the imaging.

And it would obviate methods such as
tracking.

The laser and mechanical film scanners are
very slow.

And the time it would take to take an x-ray
film, digitize that film, take the digital image, and
then use it to adjust the patient position would
exceed the actual time it would take to treat the
patient.

There are other examples, the camera system
itself introduces distortion.

And this distortion could be similar to the
deformation that could be tracked as patient motion in
the methods described in the patent.

Q I will turn your attention back to claim

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21, which is shown on the screen again.
And the same element of the claim that we were looking at also refers to portal images.
Do you see that?
A Yes.
Q And have you formed an opinion as to what a person of ordinary skill in the art in 1996 would have understood portal image to mean as used in that claim?
A I think so.
Q Would you please describe your opinion?
A So I believe a person of ordinary skill in the art at the time this patent was submitted would believe a portal image to be an image taken through the treatment portal by a megavoltage radiation beam. It would be a two dimensional image.
Q What is your opinion based on?
A I was very active in the time in portal imaging.
There was a small community of people who were actually developing imaging systems, looking at their utility and working out methods to use them. The common terminology for portal image was an image as described.
Q Did you rely on anything other than your personal experience to develop an opinion regarding

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the meaning of portal image?
A I did.
I read the patent application itself.
Q You are referring to the patent? Or the application?
A The patent itself.
Q Any other materials?
A And the prosecution history.
Q Did you find anything in the patent that informed your opinion about what a portal image is?
A I believe I did. Yes.
Q Would you please describe that?
A Certainly.
Again, if it is okay for me to quote the patent.
JUDGE ZIEGLER: Yes.
A If you go to column 1, lines 44 to 46, it says that -- I will give the whole paragraph.
"During the actual treatment phase the patient is placed in the exact same position on equipment as in simulation before the regular dosage radiation, typically in the megavoltage range, is used to treat the patient.
"During this phase another x-ray is taken which is called the portal image."

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In addition, if we go to column 4. Lines 44 to 46.
It says, "As discussed above, the simulation in the portal image can be quite different.
"One of the main reasons for this is difference in the energy of the beams."
Thus indicating the difference megavoltage versus kilovoltage.
Finally, column 5, lines 11 through 13, describes the lack of contrast due to this megavoltage imaging.
It says, "The remainder of portal image shows little detail and does not indicate location of the bones."
Q In your experience in the field in 1996 and earlier, did you use the term "portal image" to refer to kilovolt images?
A I did not.
Q And did you encounter other persons -- did you have occasion during that period to interact with other persons of skill in the art?
A Yes.
Q Did you ever hear any of them refer to a portal image as a kilovolt image?

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A I did not.
Q Back to claim 21.
The final element in this claim is a tracking means.
Tracking movement between successive sets of DPIS, which means Digital Portal Image Signals.
You were also given the task by us to identify the structure corresponding to that tracking means in claim 21.
Correct?
A That's correct.
Q And did you identify a corresponding structure?
A I believe I did.
Q Would you please describe that?
A Certainly.
This tracking means is described in some detail in the patent.
And specifically, it is schematically in figure 3.
Figure 3 shows the tracking means consists of two components.
So basically, the tracking means is most of this figure.
It starts with this calculation of rough or

coarse transformation based on x-ray opaque fiducials that are placed on the patient.

And then following this rough transformation, this loop, if we can unzoom this picture, this loop is entered where the images are prepared for fine alignment.

Fine alignment is performed using optical flow method.

Then a loop proceeds, where a new image is acquired.

And each subsequent image is analyzed with reference image, starting out with simulation image for the first alignment, being replaced by the next portal image for subsequent alignment.

And each one of these entries in the loop generates tracking output, which is intended to be used to control the linear accelerator.

Q In box 120, in this figure 3, it refers to calculating a rough approximation of the transformation.

Does the '431 patent use any other terminology to describe that step?

A Yes.

It also describes it as a coarse transformation.

Q Coarse alignment is another term that is used?

A Yes.

Q Is that a term that you had encountered in your experience in the art as of 1996?

A Yes.

I had.

Q Could you please explain?

A The concept of doing a coarse alignment prior to fine alignment was well known, especially at that time computers were not very powerful.

So in order to have a computer aid in doing very detailed calculations, it was good to make a very good -- it was useful to make a very good first guess.

So people develop methods where this first guess could be generated either automatically or with the aid of a user to help aid the subsequent fine alignment procedure.

Q And in your opinion, how does the use of the term "coarse alignment" as you encountered it in other contexts prior to 1996 relate to the use of that term in the '431 patent?

A I think it is essentially the same use.

Q And does the '431 patent describe any

particular method of carrying out coarse alignment?

A They do.

And if I am not mistaken, we made a small video.

With your permission I would like to show.

Q Before we get there, could you first identify anywhere else in the patent that describes in more detail that concept of coarse alignment?

A There are subsequent flow charts.

Flow chart 7 with pointers to flow charts 5 and 6 describe this.

This was briefly shown earlier. If we have a slide of this, we can pull it back up.

This is actually it.

The coarse alignment is generally described in flow chart 7 here.

It has components such as taking the markers and finding their centers. Described in figure 5.

And it describes how the transformation is applied to the portal image in figure 6.

Q You mentioned an animation.

A Yes.

So there is an animation. With your permission, I would like to show it.

So this describes the general scenario of the imaging that was to occur.

The image on the left is representative of a simulator image with just a little cartoon description of where the fiducials would show up.

They generally would show up fairly well in the image, although they would actually be dark.

The MV image on the right is representative of portal image. In fact, portal images at the time this patent was applied for were even lower quality than this, believe it or not.

Ideally, these images are presented so they line up one to each other relative to radiation field.

But in practice, due to either the use of film or the imager orientation, the images might be translated.

They might, in fact, be rotated relative to each other.

And it is also possible they will present a different magnification.

This is due to the fact the portal imager could be mobile relative to the position of the radiation beam.

So the first step is to present these

images in rough coordinate system that matches.
This is accomplished by first detecting these fiducials, which is generally easy to do with computer algorithms.
They show up very significant signals, very high contrast.
Once they are detected, you need to identify corresponding fiducials, so they have a one to one relationship. We know this point should be this point.
And this point should be this point.
The centers of those fiducials are then extracted.
So we would then reduce these images to just a few coordinates, which are the centers of each of these extracted fiducials.
So just these coordinates would then be used for an alignment.
This alignment procedure is relatively straight forward.
This graphic shows what generally happens.
But each of these coordinates is then magnified, translated and rotated, so that they overlay.
In the real world, the overlay would not be

perfect, because fiducials can be -- easily be placed in the exact same configuration on the patient.
And the patient's body may be slightly rotated relative to beam each time they are positioned.
Q And this represents the coarse alignment algorithm as you understand it?
A This represents the coarse alignment algorithm as I understand it.
Q If we could go back to figure 3.
What is the next step, sort of general step in the algorithm described in the patent?
A The next step after coarse alignment is this preparation step.
Where the images will be slightly modified to help with the subsequent fine alignment process.
Q Is that preparation for fine alignment described in any greater detail in the patent?
A Yes. It is.
Preparation for fine alignment is described in figure 8, if I am not mistaken.
So there are two steps to this.
The first step is to calculate a intersection between the images. Second step is enhance the images so they present with similar

information.
Q In your opinion, which if any of these steps are necessary to carry out the tracking means described in claim 21?
A As described in the patent, I believe all of these steps are necessary.
Q And actually, to go back to the coarse alignment you were describing earlier, which of those steps in your opinion, if any, were necessary to carry out the tracking function described in claim 21?
A As described in the patent, I believe all those steps are necessary.
Q Can you describe the manner in which this preparation for fine alignment proceeds according to the patent?
A We have another video, if it is okay to show.
JUDGE ZIEGLER: It is.
A So after these points are aligned, you can imagine that the images are also rotated and magnified in scale relative to each other, which means there is only specific overlap region, if we can show in the video, that has information from both the portal image and simulation image.
So to aid in the fine alignment, the

information presented is reduced to not only this information but a subset that is a simpler geometric shape such as rectangle.
The other information is discarded. And then the two images are sampled.
So the resulting images that enter the fine alignment process would be, and we will show this on the left, similar image of reduced information. We just cropped off the area that doesn't overlap.
And a portal image of again reduced information for two reasons.
We also cropped --
JUDGE ZIEGLER: A little slower.
A We can stop the video one second.
And go to the end of the video and stop it.
So the end result would be -- these images have a region of overlap.
This overlap region has a complex shape.
To help the fine alignment, the shape is reduced to a simpler shape such as this rectangular region here.
This rectangular region is sampled from the simulator image.
And the transformed portal image.
So the result are these two images with the

similar image.
Please pause.
The similar image showing the space that overlaps that rectangle.
And the portal image showing the space that overlaps that rectangle further limited in the fact there is no anatomy visible outside the treatment portal itself as well.
These images are enhanced by techniques known at the time.
So that they show similar contrast information as well as can be achieved for the different inherent contrasting images.
Q Following completion of this preparation for fine alignment, does the patent describe any other steps in the tracking process?
A Yes.
Q What does it describe?
A It describes calculation of refined image transformation and then tracking loop subsequent to that.
Q And we have figure 3 back up on the board. Could you please refer us to where you see the fine alignment?
A Calculate refined image transformation is

shown in box 160 here.
Which actually points to two flow charts. Figures 9 and 10 of the patent application.
Q And in your opinion, which, if any, of the steps shown here in figure 3 and in figures 9 and 10, if any, are necessary to performing the tracking function described in claim 21?
A Again, I believe they are all necessary.
Q And then still referring to the fine alignment process, could you please describe how the patent describes fine alignment proceeding?
A Certainly.
If we can go to figures 9 and 10.
I can show this in detail.
So figure 9 is sort of the overall loop of what happens.
In order to again help a computer do this efficiently, we actually start out by taking the images and making them blurry.
We make them lower resolution.
We reduce the amount of information presented.
And then calculate an alignment, which I will describe in more detail in a second.
And from that alignment, we use as initial

guess on a slightly higher resolution image.
We take the image. Let's say it has 100 pixels.
We down sample it by a factor of eight. Let's say 12 pixels by 12 pixels.
After we get our first guess as to how it lines up, we increase resolution, for example, to 24 by 24 pixels.
We will make a more refined guess. Then 48 pixels.
Until we get to final resolution.
Q I would like to direct your attention in particular to box 164, where it says robust optimization.
Please explain what that refers to.
A So the method of alignment.
And this is described further in figure 10 for robust optimization points to a paper by Placon and Onden that was described in the prosecution history of this application.
If we go to figure 10. This is a description of the methodology.
It has two components to it.
It has this concept of we call robust flow.
So flow is a method of aligning images so

their intensity gradients track each other.
And making robust means there is a process which I won't describe in too much detail called regularization.
And this process is designed to restrict the spatial incoherence of the motion.
The other component is this sensitivity of outliers and inliers.
This algorithm has this waiting factor that is designed to say that if some of the points move, this is a deformable alignment.
Every point can theoretically move independently.
If some of the points move excessively, they can be labeled as outliers and not influence the final transformation too significantly.
Q Would you please pull up figure 11 on the patent?
Dr. Balter, have you seen figure 11 of the patent before?
A Yes.
I have.
Q What does it represent?
A Figure 11 is also described in box 140 of figure 3.

This is the component for tracking, essentially.
It involves taking the new transformation that comes out of the coarse followed by fine alignment.
Combining it with previous transformation so we can continuously update the transformation as a new set of images is acquired.
It shows here replace simulation with current portal image.
So the first step in tracking is to align the first portal image taken in a tracking series to a simulation image.
After that alignment is done and that information is generated, this portal image that was aligned becomes a new reference image.
And it would be then aligned to any subsequent portal images required.
This also contains a box that says use this information essentially to control the linear accelerator.
Q Which, if any, of these steps in your opinion is necessary to perform the tracking function of claim 21?
A I think all of them are necessary.

Q And referring in particular to box 144 in figure 11, where it refers to generating controlling feedback signals for connected equipment, why is it your opinion that that is a necessary step in the tracking function?
A Because the patent describes that tracking is a process of using this image matching procedure to either move the system or gate the radiation beam.
Q I will now direct your attention to claim 26, which is the other asserted claim in this patent.
Have you had a chance to review this claim?
A Yes.
I have.
Q And you will note that this also refers to a means digitizing, more specifically means digitizing said x-ray image and reference image to generate first digital image signals and second digital image signals, respectively.
Have you developed an opinion regarding the corresponding structure for this digitizing means?
A Yes.
I have.
Q And how does that opinion compare with your opinion on the similar term in claim 21?
A I believe I still have the same opinion.

Q And you will note there is also a processing means, processing said first and second digital signals without input of any physical dimensions of any features within said images to generate matched digital image signals.
And have you developed an opinion regarding the corresponding structure for this processing means?
A Yes. I have.
Q And how does that relate to your testimony as you have provided it so far?
A Again, I think this requires the exact steps described in figure 3.
But used once.
And we can go to figure 3, if necessary.
Essentially, it involves calculating rough transformation, calculating fine transformation, displaying results possibly.
And then finishing.
Q Does it include that box 140?
A It does not include that box 140.
This loop is not entered in this simple matching procedure.
Q Are you aware of any publications existing prior to October of 1996, that described matching algorithms for x-ray images?

A Yes.
Several.
Q Approximately, how many that you are aware of?
A I haven't counted.
But I would have to say there are over 20 certainly by 1996.
Q Did you author any of those preOctober 1996 publications?
A Yes.
I wrote two peer reviewed manuscripts in that time period on the development and application of image registration for portal images.
Q You use the term "image registration". What does that mean?
A Image registration is another term for matching.
Q And did any of the preexisting algorithms, that you have encountered performed specific function of the processing means of claim 26, namely processing digital signals for two x-ray images without input of any physical dimensions of any features within said images to generate match digital image signals?
A Yes.
There were a few of them at the time.

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Q Are there any particular ones you have in mind?
A Well, the first one that I know of for fully automated alignment of images was from a group in the Netherlands Cancer Institute, two authors, Urin Byhold and Kenneth Hidhouse, wrote papers on methods that automatically -- extracted features that showed up as edges in images and had these features to describe a space for automatic alignment.
A group at M.D. Anderson both Jones and Boyer, and Dong and Boyer, wrote methods that just completely used all of the information automatically by correlation using 4A transforms directly.
A group in London, Ontario with Moseley and Munro, developed a method where a number of subregions were selected in the images.
And these subregions were aligned by a process called cross correlation.
Papers cited actually in the prior art and in this patent is by Radcliffe, a method called pseudocorrelation, which is a fully automated method, which used a subset of the image and developed a technique to guess at transformations such that images had similar pixel content.
And that pixel content was narrowly

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matched.
The McParland paper also referenced in this was a concept where a course in final alignment was applied and fine alignment was done automatically.
Q Does the existence of those preexisting algorithms, that you have described, affect your opinion regarding the scope of claims 21 and 26 of the '431 patent?
A Yes.
It does.
Q In what way?
A Given that there were a number of automatic, manual and what I call hybrid, which are user aided automatic procedures that were developed, published, well known at the time. It would seem that the unique aspect of the '431 patent is the very specific method described where they did this alignment.
MR. JOHNSON: Objection.
Calls for speculation.
JUDGE ZIEGLER: Overruled.
MR. POPPE: No further questions.
JUDGE ZIEGLER: Cross examine.
CROSS EXAMINATION
BY MR. JOHNSON:

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Q Did I hear you correctly that you had an understanding of what coarse alignment meant as of 1996?
A Yes.
Q What did you say it meant?
A Coarse alignment meant doing an alignment that was an approximation, a reasonable approximation.
Q All right.
And that alignment, would you consider that understanding to be something that was known by someone of ordinary skill?
A I would say so, yes. As I defined ordinary skill.
Q Look at figure 1 of the patent.
Is that figure 1 of the '431 patent?
A Yes, it is.
Q And you see the box 33?
A Yes.
Q It says coarse alignment?
A Yes.
Q You agree with me somebody of ordinary skill would understand looking at that box that what coarse alignment meant?
A Yes.
I do believe that.

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Q All right.
And they would understand that without regard to any algorithm, isn't that correct?
MR. POPPE: Objection.
Vague.
JUDGE ZIEGLER: Overruled.
A Can you describe -- can you describe that in more detail?
That question in more detail.
Q No.
Somebody of ordinary skill in the art, looking at box 33, using your understanding -- I am only asking, they would understand that without requiring the need to look at any algorithm, wouldn't they?
A They would not be able to determine how effective the coarse alignment is without knowing the methodology.
Q I didn't ask you about effectiveness, Doctor.
I asked you, they would understand that without regard to looking at any algorithm.
Isn't that right?
A They would understand from the words coarse align, a rough alignment is to be done.

Q All right.
And you understood that there were different ways of doing a rough or coarse alignment back in 1996.
Correct?
A Correct.
Q You also understood that somebody of ordinary skill in the art looking at figure 1 would have understood what a fine alignment was?
A Most likely, yes.
Q And you also understand by looking -- simply at figure 1, not referencing any algorithm, they would understand that there were techniques available to allow one to do a fine alignment. Correct?
A They would understand that a number of other investigators had developed techniques, which were published and well known at the time.
Q All right.
So in your opinion, based solely on figure 1, someone of ordinary skill in the art would be able to determine a coarse alignment was required using an approach to accommodate that, and would also understand a fine alignment was required and use an approach to accommodate that?

MR. POPPE: Objection.
Compound.
JUDGE ZIEGLER: Overruled.
A I believe they would understand that.
Q Now, I want you to look at box 29.
It says digitizer.
You told us that there were a number of digitizers on the market on or before 1996.
Correct?
A Correct.
Q And I believe you told us that some of those digitizers would not be suitable for use in this particular application.
Correct?
A Correct.
Q Somebody of ordinary skill in the art would understand that there were digitizers that were suitable for this particular application.
Isn't that right?
A Without having enough knowledge of the details of the algorithm, this graph alone would not be able to determine whether there is sufficient digitizer, actually.
Q Isn't it true, sir, that if I am somebody of ordinary skill in the art, and the problem to be

solved is to deal with coarse and fine alignment, and I need to digitize an image, that I could select a digitizer that would accomplish that result?
A I am not convinced, actually.
Q Well, would a digital camera allow you to take a picture of the patient and convert the analog image to pixels, which would enable you to do a coarse alignment?
A It could enable me to acquire an image of a patient.
It may allow me to do coarse alignment.
It depends on image quality of that image.
Q That's right.
So if I had a 4.0 megapixel camera, and I took just -- that I bought from I don't know which stores you have out here, Fry's where I come from, and took a picture, that picture would convert an analog signal, which is how we see the world in to digital, basically pixels, and I could feed that information in to that processor and do a coarse alignment.
Correct?
A I would need to know what lens is involved.
And certainly at the time this patent application was filed, four megapixel cameras were not

a common device.
Q Well, call it a one megapixel camera.
A I would still worry about lens distortion associated with this.
Q It is true, is it not, someone of ordinary skill in the art would have the ability just like a lay person such as myself to select the lens that wouldn't result in a distorted image?
A No.
All lenses have distortions.
Q Okay.
An image that would be sufficiently distorted so it would render you incapable of doing this coarse or fine alignment?
A The fine alignment is of grave concern. Because the fine alignment in theory goes beyond the level of distortion of a typical lens.
Q It is simply a matter of the contrast, isn't it?
A No.
I mean, light bends through a lens.
So if I take a piece of graph paper, take an image of it through a lens, I don't get regular piece of graph paper out, I get a bent image.
Q But that image can be clearer than other

bent images.
Correct?
A What do you mean by clearer?
Q I mean clearer to you as the viewer.
A I don't understand the question.
Q Well, if you have a fuzzy image and an image less fuzzy, I will call it clearer.
Are you telling me that if I have a fuzzy image and one less clear, you don't understand what that means?
A I understand a blurry image and a sharper image.
Q So if you have a sharper image as contrasted to the blurry image, that would constitute fine alignment to one of ordinary skill in the art. Wouldn't it?
A No.
Fine alignment means accurately getting a transformation that goes throughout the image.
It involves a process of deformation.
And if the lens itself induces a deformation, that deformation could be misconstrued from a perfectly visible image as patient deformation when it is in fact not.
Q If you select the lens that doesn't have

the deformation, then you solve that problem.
Haven't you?
A No lens has no deformation.
It is the way optics works.
Q So if I understand what you just told me then, it is impossible to do fine alignment, because no lens does not have deformation, is that it?
A No.
You asked me a question about the nature of a camera based digitizer.
Q So you are telling me you can't have a camera based digitizer?
A I am saying you need to do extra work with a camera digitizer not specified in this patent to fix lens distortion.
Q You know Mr. Munro, don't you?
A Dr. Munro, yes.
Q Are you familiar with his articles written by him?
A Reasonably so.
Q Were you aware he made specific reference to making portal films using our TV camera and frame grabber as a video digitizer back in 1989?
A Absolutely.
Q You think that is something that was known

at the time to use a TV camera and a frame grabber as a video digitizer?
A It was known as a digitizer, yes.
Q And you could use this video digitizer to accomplish this coarse and fine alignment?
A I am not convinced I can accomplish fine alignment with a --
Q Are you convinced you couldn't?
A I am convinced there is not enough information in this patent that would make it possible to do it.
Q Now, let me ask you to, if you will, you were talking about tracking movement.
Do you recall that?
A Yes.
Q Would you put up column 3 for me, please?
If you will go to line 29.
It says, "In the tracking mode, the updated transform is used to track movement between successive sets of digital portal image signals."
A Yes.
Q What do you understand tracking to mean in the context of that sentence, sir?
A So the context of this is that if a patient moves, the idea of the tracking system is to detect

that motion.
Q And it says, "Tracking can be used to terminate the radiation, if patient movement exceeds specified limits. Or could be used to operate the patient positioning assembly to maintain the radiation beam in proper alignment with the area to be treated."
A Yes.
Q In other words, tracking means what it says.
You are tracking movement. The patient movement.
Correct?
A Yes.
It tracks the movement of the patient.
Q And somebody of ordinary skill in the art reading that language would understand that to be the case.
Correct?
A I believe so.
Yes.
Q Thank you.
Now, could we look at column 4, please?
Lines -- I think that is 37.
You told us about portal image. Recall that?

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A Yes.
Q It says, "Following completion of the simulation, the patient 3 is transferred to the treatment setup 1. As shown, the treatment setup at 1 is similar to the simulation setup 1, except that the x-ray beam 11 prime is in the megaelectron volt range. A portal image is generated by the treatment setup 1. This portal image can be captured by an x-ray film as in the simulation setup. However, it is preferred that an electronic portal imager 25 be used. If available, an electronic imager could also be used in place of the x-ray film 23 in the simulation setup 1."
See that language?
A I see that language.
Q Now, is there anything that says that the image in this portal image is limited to megaelectronic volt range?
A It says except that the x-ray beam is in the megaelectron volt range.
Q Correct.
But does it say it has to be in the megaelectron volt range?
A It says, "As shown the treatment is similar except that the x-ray beam is in the megaelectron volt range." I don't understand any other interpretation.

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Q Let's see if I can help you out. Go to column 1, if you will, please.
If you will, go to lines 40 through 46.
It says, "During the actual treatment phase, the patient is placed in the exact same position on the equipment as in the simulation before the regular dosage x-ray radiation, typically in the megaelectron volt range, is used to treat the patient. During this phase, another x-ray image is taken, which is called the portal image."
See that?
A Yes.
Q Now, in looking at the definition, or I should say the description of this x-ray, does it limit itself to particular voltage?
A It suggests megaelectron volt range.
It does it in a couple of places.
Q Now, when you were telling us about the algorithm, I want to go specifically to one that you pointed out.
I believe it is figure 3.
You said -- if I understood you correctly, all of these steps were required in order to accomplish this particular result.

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Correct?
A Could you describe which particular result?
Q I think this was your tracking means.
A Yes.
So I believe that I did not mention box 110.
I did not mention transform and display images.
And the end.
I described the loop that started at 120, went through these stages and went back through here.
Q Did you look at the claims in the patent, sir?
A I did.
Q Did you have an understanding that they were dependent claims?
A Could you describe dependent claims?
Q I am asking if you have an understanding.
A Barring a definition of dependent claims, I came to understand that they described one complete invention.
Q And did you have an understanding that the patent specification and drawings had to cover all of the elements of the claims, to support all of the claims that were listed in the patent?

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A I can imagine that is the case.
Q So you understood there wasn't one giant claim here.
There were numerous claims.
Correct?
A Yes.
Q And you could look at different parts of the specification in the drawings to find support for each individual claim. Correct?
A Absolutely.
Q So it is not your testimony that for purposes of -- that this drawing was limited to covering only the tracking mean for all of the claims. Is it?
A It is not my testimony that every element in this drawing is necessary for the tracking claims, specifically this 110.
JUDGE ZIEGLER: Anything further?
MR. JOHNSON: Nothing further.
JUDGE ZIEGLER: Counselor.
MR. POPPE: A couple questions, if I may.
JUDGE ZIEGLER: You may.

REDIRECT EXAMINATION

BY MR. POPPE:
Q If you could bring up figure 1 again,

please.
Dr. Balter, do you recall Mr. Johnson asking you a couple questions about this figure?
A Yes.
Q And referring in particular to the box in the middle labeled coarse align, box No. 33, do you see that?
A Yes.
Q You were asked a question about that.
A Yes.
Q Now, you testified that you are aware of multiple ways of performing coarse alignment. Is that correct?
A Correct.
Q And in your opinion, would a person of ordinary skill in the art in 1996 reading the entire patent including all of the figures and all of the text understand that any coarse alignment mechanism could be used to perform the tracking function described in claim 21?
MR. JOHNSON: Leading.
JUDGE ZIEGLER: Overruled.
A I don't believe so.
Q Why is that?
A The '431 patent describes a very specific

method.
And it specifically says a couple things.
Including in the prosecution history.
It says without input of any physical dimensions of any features.
Which would mean that it has to be completely automated.
And if you specifically look at the patent.
It actually describes that the rough transformation comes directly from this alignment of the radio-opaque markers.
Q If I put the same question to you with respect to the processing means and the processing function of claim 26, what would your answer be with respect to coarse alignment?
A So again, it specifically has to point to the structure described in the patent application.
Q Now, on a different topic, you were asked a question about whether tracking as described by the patent refers to the tracking of patient movement.
Do you recall those questions?
A Yes.
Q And do you recall hearing some testimony from Dr. Schell, that tracking could cover the tracking of different patient positions during

different treatment fractions occurring at different points in time?
MR. JOHNSON: This is beyond the scope of cross.
JUDGE ZIEGLER: Overruled.
A I recall hearing that.
Q Do you agree with that testimony of Dr. Schell?
A I am afraid I have to respectfully disagree.
Q Could you explain?
A The system describes tracking in order to control the radiation equipment by adjusting position, by turning the beam off.
First of all, tracking itself was a commonly used term in 1996 for motion that occurs during a single treatment session, intratreatment motion.
Second, using a measurement today to control a couch tomorrow doesn't make sense.
There are large number of variables involved in patient positioning.
And using this transformation to so called track between subsequent inspections in control of the accelerator simply wouldn't work.

MR. POPPE: No other questions.
JUDGE ZIEGLER: Mr. Johnson?
MR. JOHNSON: I didn't understand the last response.
RECROSS EXAMINATION
BY MR. JOHNSON:
Q You track patient movement, either breathing, correct?
JUDGE ZIEGLER: You have to answer yes or no.
A Yes.
Q Or you can track patient movement by repositioning.
Correct?
A Okay.
So the first thing you said is tracking as in measurement, which is measuring or observing breathing motion.
The second thing you said is controlling patient equipment, which is a separate component traction, which is reaction to a measurement that you make.
Q So I was right?
A Those are separate things.
Q That's right.

And your last response was talking about patient movement as it relates to positioning. Correct?

A No.

Tracking movement means tracking within a specific time period.

Tracking contains two components. Monitoring and reaction.

And monitoring is specifically designed, and it was known at the time as intratreatment motion.

Q Can you show me anything in the '431 patent that says tracking is limited to a specific period in time?

A It does not say a specific period of time.

Q It doesn't even discuss it, does it?

A It does not discuss a period of time, although it uses the term "movement". And the term "tracking".

MR. JOHNSON: Nothing further.

JUDGE ZIEGLER: Thank you, sir. You may step down.

Counselor, do you have another witness?

MR. POPPE: My colleague Ms. Zheng Liu does, your Honor.

JUDGE ZIEGLER: Would you come forward, sir.

DR. STEVE JIANG

called as a witness by the defendant, having been first duly sworn, as hereinafter certified, was examined and testified as follows:

JUDGE ZIEGLER: State your name.

THE WITNESS: Steve Jiang.

JUDGE ZIEGLER: Spell your last name?

THE WITNESS: J-I-A-N-G.

DIRECT EXAMINATION

BY MS. LIU:

Q Dr. Jiang, please speak loudly so the court reporter can record what you say.

JUDGE ZIEGLER: And keep your voice up, please.

THE WITNESS: Sure.

Q Dr. Jiang, briefly explain your professional experience starting from your Ph.D. training?

A Sure.

I got my Ph.D. in medical physics in 1998 from Medical College of Ohio.

And then after that, I went to Stanford University, received my post doctoral training for two years.

And then I became an assistant professor at Harvard medical school until early this year in February 2007. This year, I joined University of California, San Diego, to become an associate professor with tenure and also director of research at the department of oncology.

Q Do you have any specific experience in respiratory gating?

A Yes.

I do have a lot of experience in respiratory gating.

And also motion management.

Because that has been my research focus since year 2000.

And I have published about -- in my whole career, I have published about I think more than 60 peer reviewed journal papers, about 50 percent of that are in field of respiratory gating and motion management.

And also in the past two years, I have given I think about 35 invited talks all over the world.

And all of them are in this field.

Q Do you have any experience with computer software programming?

A Yes.

I started to write computer software about 20 years ago.

And since then it has been very important part of my research.

So I do have a lot of experience.

Q So you have -- do you have a good understanding of algorithm and how algorithms function?

A Yes.

Q Exhibit A, attached to the No. 2 in the folder is a document.

Dr. Jiang, is this an updated copy of your CV?

A It is updated until August.

MS. LIU: Your Honor, we move the CV in to evidence.

MR. JOHNSON: No objection.

JUDGE ZIEGLER: Admitted.

MS. LIU: Also move to qualify Dr. Jiang as an expert in the field of respiratory gating.

JUDGE ZIEGLER: Mr. Johnson, any questions?

MR. JOHNSON: For purposes of this hearing, I have no questions and no objection.

JUDGE ZIEGLER: Motion granted.

BY MS. LIU:
Q Dr. Jiang, do you have a copy of the '554 patent?
A I do.
Q Have you reviewed this patent?
A Yes.
I have.
Q Have you formed an opinion, on what is the technical field of the '554 patent?
A Yes.
I have.
In my opinion, the technical field includes medical physics and computer vision.
Q Have you formed an opinion on the level of education and experience that a person of ordinary skill in the art would have had in 1996?
A Yes.
I have.
Q What is your opinion?
A My opinion is there are two types of people can be qualified as a person of ordinary skill in the art in 1996.
The first type is a person with a master's degree in medical physics and some years of professional experience in computer vision.

And second type is a person with a bachelor's degree in computer vision and some years of medical physics experience.
Q Why do you think a person of ordinary skill in the art would have that combination and level of experience?
A That is because this patent '554 is all about to use computer vision techniques to solve radiotherapy problem.
Q Was the concept of gating, turning radiation beam on and off following the patient's breathing, was that concept known to the research community in 1996?
A Yes.
Q Was there any known techniques for respiratory gating prior to the finding of this '554 patent?
A Yes.
Q Would you please describe these techniques?
A There were a few publications before September 1996.
One work was published by a Finnish medical physicist in 1986.
And then around the same time he also filed a patent in Finland.

And another work was published by Japanese group in 1989.
And then there were two publications in 1996.
One from an Italian group.
And the other from UC Davis, Dale Cooper's work.
And they use different ways to track the chest movement.
Therefore, track patient movement to generate the gating signals.
Q Were these techniques well known in the field?
A Yes.
Q Did any of those techniques specifically involve using video cameras and fiducial markers to determine movement of a patient?
A Yes.
The Italian group used fiducial markers attached on patient's body, also used video cameras to track the chest movement.
The Finnish work used laser projecting on patient's skin as a fiducial marker. And they use video camera to track that.
Q Would you please take a look at claim 20 of

this patent?
A Yes.
Q Did you see the first element refers to a camera means?
A Yes.
Q Have you formed an opinion how a person of ordinary skill in the art in 1996 would understand the term "camera means" to be?
A Yes.
Q What is your opinion?
A My opinion is a person of ordinary skill in the art in 1996 would think camera means are regular video camera captures gray scale image of patient under the visible light condition.
Q Please explain the basis of your opinion?
A In terms of the camera itself, in the patent, you mentioned it can be CCD camera, regular video camera.
I mentioned why it is visible light condition.
Because also it mention in the patent that the fiducial markers have lambertian surface.
And so if you have regular video camera and if you have fiducials with lambertian surface, the only thing you can see in the image is visible light,

not the invisible part of the light spectrum.
Q Can the natural fiducials be seen under visible light?
A Yes.
Visible light.
Yes.
Q Can natural fiducials be seen under invisible light spectrums?
A It cannot.
In theory, you can use camera to get some signal of invisible light.
But the signal is so weak, it is totally useless.
I don't believe a person of ordinary skill in the art will think this camera will capture invisible light and use that to track the patient movement.
Q Can you also still look at claim 20, and there is another phrase called means -- starts with means determining movement?
A Yes.
Q Have you formed an opinion whether the patent specification describes a structure that corresponds to the means determining movement of said patient from said digital image signals?

A Yes.
Q What is the structure?
A The structure is a computer process that is programmed with computer algorithms to track the fiducial movements and therefore track the patient movements.
Q What are the algorithms you refer to?
A The algorithms are described in the patent using flow charts, also of course in the text.
The flow charts are from figure 6 all the way up to figure 16.
Q Is there any major steps defined by the algorithm?
A Yes.
If you look at figure 6.
This is the figure that describes the whole process.
Including several algorithms.
And in my opinion, there are five major steps.
The first one is detect the fiducials on the patient body using current camera image.
So that is step 1.
And after you detect fiducials, then you can fine tune the tracking templates for the current

patient and for the current treatment decision under the current condition.
Then the third step -- then you track the fiducial in new image.
That is box 140.
And during this process you may find the fiducial is last.
So that is the box 150.
You have to have an algorithm to see if the fiducial is lost or not.
If the fiducial is lost, then you have to reacquire the fiducial in the image in a larger image.
That is the box 180.
Those are the five major algorithms.
Five major steps for this whole tracking process.
Q The steps you described and defined by the algorithm, are there any that are necessary to perform the function of determining movement of the patient from the digital image signals?
A Yes.
Q What are they?
A All of them are necessary.
Q Why are all of them necessary?
A Because as I mentioned before, the patent

uses regular video camera.
And under varying lighting condition, and also the fiducials may have different shape and different size, different appearance, which it says in the patent, therefore, you need all these algorithms to be able to track the fiducials.
Q Did you create an animation to --
A Yes.
I helped create an animation to explain this part of the process.
If I may show the animation.
JUDGE ZIEGLER: Fine.
A So this is a patient lying on the treatment couch.
And for this patient, assume we have two artificial fiducials here and here.
And then there is natural fiducial which is a scar.
And then we have a mole here, which has an appearance similar to the artificial fiducials.
And when the patient breathes in and breathes out, so if you can stop here, then you can see these are the fiducials can move closer to each other or move away from each other.
So they don't have a relationship with each

other.
And then using the camera attached to the treatment machine, we can capture two dimensional gray scale image of the patient.
In the image we do have fiducial markers here.
And if you can stop here, so as stated in the patent, this technology is going to be used under different lighting conditions.
So in the regular radiotherapy treatment zoom, you have different sets of lights like regular lighting condition like this.
Sometimes we turn on all lights.
Sometimes we turn some of them on.
Sometimes we turn them off in order to see. So different conditions there.
And under common condition like this, the brightness of the fiducials are very similar to that -- is very similar to that of the background, which is patient body and treatment equipment and the zoom itself.
So therefore, it is difficult to track the fiducials, to detect the fiducials first, and to track them under different lighting conditions.
And therefore, we need algorithms to

perform this task.
So the first step is to downgrade the image in to low resolution.
And then you can do so called rester scanning, using initial idealized template from in previous days or different patient.
When I say rester scanning, meaning scan from left to right, up and down, and you can skip some.
They can identify some candidates for fiducials. In
This case, we found three candidates. This is a mole.
Then you do this for other fiducials like the natural fiducial.
And then you can detect the scar here, as a natural fiducial.
After that, the next step you go back to high resolution mode.
And then you perform a series of operations including normalized correlation.
Sparse sampling again.
And bracketing and interpolation.
And minimal separation.
After that, you can remove the false

fiducial, which is the mole here.
And find the true fiducial.
Then you can obtain more realistic template for this treatment for this patient.
That is called a fine tuning of the template.
And that is an important step of the algorithm.
Q Dr. Jiang, is this animation represents what you understand for the phrase "means determining movement of patient from digital image signals" to be?
A Yes.
This animation explains the -- if you look at figure 6 in the patent, it explains 1, 2, which is 110 and 120, two boxes.
Q What are the key features of the algorithms as described in the patent you just showed all these steps in the animation.
What are the key features?
A The key features, like I mentioned, normalized correlation, template matching, different levels of resolution.
Featuring all key features.
Q Why do you consider them to be key features?

A Because you need them to track -- detect the fiducials and track them under the different light conditions and also different appearance and shape of the fiducials.
Q Would you please take a look at claim 21, please?
In the third sentence, did you see a phrase "fiducial on said patient"?
A Yes.
Q Have you formed an opinion regarding what a person of ordinary skill in the art would understand the term "fiducial on said patient" to be in 1996?
A The understanding of the person of ordinary skill in the art would be fiducials are both natural and artificial are attached to the patient body, individually.
Q Why do you believe that the fiducials are attached to the patient's body, individually?
A Well, if you look at the figure 2.
And also figure 5.
You can see fiducials are individually attached to the patient's body.
And also it was common practice to do so around 1998.
Like I mentioned, this work from the group,

they did similar work, fiducial markers attached to the patient's body.
Also, I am aware of work done by Harvard medical school, Dr. New.
He did similar work around that time.
He got a Whitaker grant for that work. It is the same idea.
Attach fiducial markers individually on patient body.
Also I believe there is reason for that, why people did that around that time.
The reason is they try to capture different movement of the different parts of the body.
Therefore, they don't want to have rigid relationship or mounted fiducial markers.
That is why I think ordinary -- person of ordinary skill in the art in 1996 would think fiducials are attached to the body, individually.
Q Is there anywhere in the specification described that the fiducials are individually attached?
A There are places.
I can point to one.
If you look at column 3, line 65.
So there you see, "It is advantageous to

provide multiple fiducials placed on the patient so as to detect any movement of the critical locations."
Meaning you want to attach fiducials individually to get any movement of critical locations.
Different parts of the body.
Q Did you create an animation?
A There is another animation showing this.
So in this we have four artificial fiducials. And one mole.
Patient breathes in, breathes out, how the fiducials move relative to each other.
And then stop here.
So this is the end of exhale, when the patient breathes out, they tend to stay there a little bit longer.
So this is the most stable and reproducible phase for most of the patients.
This was discovered by Dr. James Balter many years ago.
Since then common practice in our field is to treat the patient at this particular breathing phase.
In this case, we colored fiducials in green.

Meaning we are going to treat the patient at this point.
Turn on the beam.
And now when the patient breathes in, the fiducials will move outwards.
So when the distance of the fiducials exceed the first tolerance, then we color fiducials in yellow, meaning we will generate a warning signal.
But we still treat the patient at this time.
So now if the patient breathes in, at this point fiducials are in red, meaning they are too far away from the treatment position.
So we should not turn on the beam at this point.
That is why we turn them in red.
And you see we need to develop algorithms to record and compare different spatial patterns of the fiducials in order to be able to detect the breathing signal to generate signal. See how it works.
And here if you stop here, you see green and yellow and red similar to the traffic lights.
This is mentioned in the patent.
If you look at figure 5 in the patent.

You have three different colors it says in the text.
Similar to traffic lights.
Also in the text, column 5.
So there you also see the same thing about the traffic light, how you convert the spatial pattern change in to this traffic light kind of signal.
If you continue.
Now from the spatial pattern change, we can generate this kind of signal.
And this signal, when it is in yellow or green area, you turn on the radiation beam.
So this is how it works based on the understanding of a person of ordinary skill in the art in 1996.
Q Dr. Jiang, would you please show the board where in the specification describes the algorithm you just explained?
A That would be in figure 16.
You can see there it mentions -- compares spatial pattern of the actively tracked fiducials.
This box.
Q Is there anywhere in the specification describing the traffic lights you were just mentioning?

A Figure 5 also in text, that would be column 5 from line 4 to line 13.
That paragraph.
Also in paragraph -- column 4. Go to column 4.
The last paragraph. It also describes.
Just reading this right now.
The whole paragraph is talking about traffic lights, if you read it.
It says here traffic light turns red.
Q So was the animation you just showed the court, does that animation represent what you understand of the algorithm to mean?
A Yes.
Q Is there anywhere in the patent describing fiducials that are not individually attached?
A No.
MS. LIU: No further questions.
JUDGE ZIEGLER: Cross examine.

CROSS EXAMINATION

BY MR. JOHNSON:
Q You just said there is nowhere in the patent that describes fiducials that are not individually attached.
Is that right?

A That's correct.
Q Let's take a look at the claim, if you will.
And let's go to claim 21.
I would like you to highlight the third line, if you will, "At least one fiducial on said patient".
See that language?
A Yes.
Q That language doesn't say physically attached on said patient.
Does it?
A No.
Q And let's go back to your column No. -- that you looked at.
I believe it is column 3, line 65.
I think you went over to column 4.
A Yes.
Q And let's highlight the language 65 through 67.
It talks about multiple fiducials placed on the patient.
Correct?
A Yes.
Q You can place fiducials on the patient in a

variety of ways.
Can't you?
A Yes.
Q And enumerate them for his Honor?
A You can place them individually on the patient's body.
Also you can place them on like a carrier.
Then put a carrier on the body of the patient, therefore they have a rigid relationship.
Q Both would be on the patient.
Correct?
A Right.
Q Both would enable you to practice the patent by tracking movement.
Correct?
A Correct.
Q Now, you told us, I believe, that the camera had to be a video camera.
A I think it said in the patent it is a video camera.
Q It doesn't say it has to be a video camera in the patent.
Does it?
A It says -- it doesn't say it has to be video camera.

But it says it is a video camera.
Q I wanted you to help me out here.
Let's go to column 4.
And if we go up to about line 7.
It says figure 4.
It says, "Figure 4 is a functional diagram of the invention. The cameras 35 capture an image of the fiducials on the patient reclining on the patient positioning assembly 23. The image captured by the camera is digitized by digitizer 45 to generate digital image signals."
Then it talks about the gray scale for each camera pixel.
Is that correct?
A Yes.
Q Can you show me where it says that camera has to be a video camera?
A I don't know any other type of camera. If camera is used to generate gray scale image, that is video camera, in my opinion.
Q Can you convert the gray scale using a digitizer?
A Yes.
Q Now, you were aware of the existence of digitizers that could be used to convert to gray

scale, weren't you, back in 1996?
A Yes.
Q I would like you to go to column 2, if you will.
Just spend a second on gating.
And let's go up to lines 13 through 21.
It says that, "Another aspect of the invention, the means determining movement of the passive fiducials includes means detecting movement associated with patient breathing and random movement.
"The movement associated with patient breathing can be used to generate a gating signal synchronized to patient breathing.
"This gating signal can then be used to actuate the beam generator only during selected parts of the breathing cycle."
Have I read that correctly?
A Yes.
Q If I understand it, this gating signal allows you to actuate this beam generator, so that the beam will either be on or off.
Correct?
A Correct.
Q That is what it does?

A Yes.
Q Now, there are a variety of ways that will enable one to turn the beam generator on or off. Correct?
A Correct.
Q And there were different approaches known to accomplish that result back in 1996.
Correct?
A True.
Q Now, you understood from the patent, did you not, there was a difference between an alarm and a gating signal?
A Yes.
Q And that difference is that the gating signal actuates the beam generator and an alarm can either be visual or audible, if something bad happens during the process.
Right?
A That's right.
Q So the two are different.
A That's right.
Q Now, you are not contending, are you, that an alarm and a gating signal have to work together for purposes of practicing the patent?
A Based on the way the patent is written,

they are working together.
Q Did you look at the individual claims? Again, I will direct you to claim 20.
Which is found on column 10.
If we are looking at this processing means, there is a reference, is there not, line 49 to gating means generating gating signals synchronized with said movement associated with breathing by said patient. Do you see that?
A Yes.
Q That gating signal referred to there is not an alarm.
Is it?
A No.
I don't think so.
Q And it is true, is it not, there is no reference to the alarm in this particular claim?
A True.
Q You are not telling us, are you, that that gating signal requires an alarm to satisfy the elements of claim 20.
Are you?
A No.
Q Thank you.
You told us that the camera required

visible light.
A Right.
Q There is nothing in this patent that makes a reference to visible light.
Is there?
A What is in the patent exactly, if you look at figure 1.
This is like a common setup.
They don't have spatial invisible light source.
Without spatial invisible light source such as the one used in prior art, they cannot get image of invisible light using the camera like CCD camera.
So I would think a person of ordinary skill in the art in 1996 would think you can't use any invisible light.
It has to be visible light.
Q Well, they are using x-rays.
Aren't they?
A To treat the patient.
Q To treat the patient?
A Not to track the motion.
Q But they are also using x-rays to grab a portal image, aren't they, as part of the process?
A In that case, yes, that is true.

In that case, portal image is detector. In this case, it is camera is the detector.
Q My question to you, sir, you understood that the entire assembly, let's look at one, if we have one here, if we look at just the front of the patent.
There is a picture at the bottom or figure 1, whichever is easier.
That is the apparatus we are talking about, isn't it?
A That's correct.
Q And they were using -- we are capturing images of x-rays, correct?
A Using the camera?
No.
Incorrect.
Q I am asking you for purposes of this apparatus, are you capturing x-ray images?
A For this patent to track the patient movement?
Q No.
Just generally.
Generally using this apparatus to treat a patient, you are going to capture x-ray images. Aren't you?

A I would say yes.
If you use a machine like this, you can capture x-ray images using the portal imager.
Q Did you look at the file history in your review?
A Yes.
Q Did you see where the examiner was relying on prior art that used a camera that could capture infrared images?
A I look at it very briefly, yes.
Q But you understood that was part of the prior art that the examiner relied on to define cameras, including something that captured infrared?
A I understand the camera used in the prior art is the same camera.
However, they also have additional piece. That is the infrared light source, which is very close to the camera.
Without that kind of lighting source, the cameras cannot be used for infrared.
Q Sir, two questions.
First of all, the use of this infrared light source was well known in 1996.
Correct?
A In prior art, yes.

Q I am talking about to somebody of ordinary skill in the art.
A Yes.
Q And so therefore, somebody of ordinary skill in the art would understand if they needed to add this infrared for purposes of capturing images, it could easily do so?
A That is another piece of equipment.
Also for the fiducial markers, you described in the patent don't work, because fiducial markers have lambertian surface. You need reflective surface in order to use that light source to capture motion.
Q But it is true, is it not, that one of ordinary skill would have no difficulty using an infrared ring or some other application to view infrared images?
A It is true.
Q And it is also true that there is nothing in this patent that says you can't do that, is there?
A In this patent, it says it does not have that critical piece.
Also, it has one fiducial marker, so you cannot do that in practice.
Q Isn't it true that the claim says "at least

one", and there may be multiple markers?
A Yes.
Q So you understand that you can have more than one marker?
A Right.
Q And you understand that because you can have more than one marker, there may be different images you may need to acquire?
A It says in the patent they are all same type of artificial fiducial markers.
They have the same surface.
Q One last point.
There is a difference between an artificial fiducial and a natural fiducial.
Correct?
A Correct.
Q And tell the judge what that difference is?
A The difference is an actual fiducial marker based on this patent is part of the patient's skin, like a scar.
Unnatural fiducial is something like an object you made with spatial shape, like circle shape and place that, attach that to patient's body.
Q And somebody of ordinary skill in the art, you understand, do you not, a fiducial can be either

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natural or artificial?
A Yes.
Q So when you look at, for example, claim 21, we were just there, where it says at least one fiducial, you would agree with me that means it could either be unnatural or an artificial fiducial, isn't that right?
A True.
Q Nothing further.
JUDGE ZIEGLER: Any rebuttal or redirect?
MS. LIU: A few questions.
JUDGE ZIEGLER: Go right ahead.

REDIRECT EXAMINATION

BY MS. LIU:
Q Dr. Jiang, is there a rigid carrier disclosed anywhere in the patent?
A No.
Q According to your expert opinion, does the algorithm contemplate the use of a rigid carrier for fiducials?
A No.
The algorithm was designed to track the fiducials, because we were talking about a lot of things, to track -- how to track them individually. If they are rigidly attached, the algorithm will be

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much simpler, in my opinion.
Q Was there any mentioning of infrared light in the specification?
A No.
Q Was there any mentioning of any other -- using any other invisible light source in the specification?
A No.
Q Counsel just asked you a question about using the assembly, figure 1.
Counsel asked you for this linear accelerator, whether it is possible for the electrical -- electric portal imager to capture an image of x-ray.
MR. JOHNSON: Objection. Misstates my question.
JUDGE ZIEGLER: Overruled.
Q Do you remember that question?
A I do.
Q So for this setup disclosed in the patent, if you use the electric portal imager to capture x-ray image, was that for the purpose of -- that was contemplated by the algorithm?
A No.
Q So what does the algorithm require?

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A The algorithm requires fiducial markers and also using camera to track the fiducial markers.
Q The fiducial markers disclosed in this patent, are they x-ray opaque fiducials?
A It can be opaque.
It cannot.
Either way is fine.
So the patent did not specifically say anything about the fiducial.
Q For claim 21 earlier, counsel highlighted the phrase "at least one fiducial on said patient".
And counsel asked you whether there were any specific mentioning of this in this sentence whether individually placed.
Do you remember that question?
A I do.
Q What would a person of ordinary skill in the art looking at a claim and the patent understand what a fiducial on said patient to be?
A It would be fiducials with lambertian surface.
That is the artificial fiducials.
Also can be natural fiducials.
Q Are they individually attached?
A Yes.

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Individually attached on the surface.
MS. LIU: No more questions.
JUDGE ZIEGLER: Anything further?
MR. JOHNSON: Nothing.
JUDGE ZIEGLER: Thank you.
You may step down.
It is 12:30.
What is your pleasure?
MR. ANTHONY: What is your pleasure?
JUDGE ZIEGLER: We completed Varian's presentation.
Mr. Johnson is entitled to rebuttal. Do you present rebuttal?
MR. JOHNSON: I do.
JUDGE ZIEGLER: Let's recess for lunch for one hour.

(Thereupon, a luncheon recess was taken from 12:35 o'clock p.m. until 1:35 o'clock p.m.)

A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N
JUDGE ZIEGLER: Mr. Johnson, you may proceed, if you are ready.
MR. JOHNSON: Dr. Schell, please.
REDIRECT EXAMINATION
BY MR. JOHNSON:
Q Dr. Schell, you were here this morning and heard the testimony concerning need for the use of all of the algorithms in the '554 patent.
Do you recall that testimony?
A Yes.
I did.
Q And do you agree with it?
A I agree to the extent that that particular flow chart design, those steps are necessary.
Basic algorithm is in figure 4.
Q Let's put figure 4 up for the court.
A Patient motion detection and gating signal generator.
But the problem is one could design other flow chart designs to achieve the same goal.
Other algorithms.
So the essence of the patent is figure 4. And the flow charts that follow are one example of achieving those goals.

Q And let's turn to the '431 patent.
I will ask you the same question.
You heard the testimony concerning the use of all of the steps of the algorithms in order to practice the patent.
A Yes.
I did.
Q And did you agree with that conclusion?
A I agree to the extent that again, that the steps listed are necessary.
But there is other ways to achieve figure 1.
Q And you have on the screen figure 1.
A Coarse and fine alignment.
Q And why is this significant?
A Well, because the algorithm of the patent is coarse alignment, fine alignment to achieve the goals of the patent application for matching x-ray images with reference images.
But it is conceivable to design different approaches to achieve the same goal.
Q Now, there was testimony about whether or not in the -- I think it is the '431.
The camera had to be -- I am sorry, '554, the camera had to be a video camera on visual

spectrum?
A That is not necessarily true.
Q Tell me why.
A There is examples of infrared cameras that were in use to track surgical instrumentation in the early '90s.
These infrared cameras had infrared lamp source to illuminate infrared markers to follow the motion of the instrument in question.
It was later applied to the brain lab exact tracks system.
So that you have two cameras, infrared, looking at fiducial markers.
The infrared lamps in each camera were irradiating markers.
And you could track those markers and infer where the tumor position is.
At the time of the patent.
MR. JOHNSON: Nothing further.
JUDGE ZIEGLER: Any questions, counselor?
MR. POPPE: No.
JUDGE ZIEGLER: No questions.
You are excused.
Thank you.
MR. JOHNSON: Now it is time to argue the

terms.
JUDGE ZIEGLER: All right.
We discussed the order. Varian proceeds first.
You proceed last.
Is that correct?
MR. JOHNSON: That works for me.
JUDGE ZIEGLER: That was my recollection of the conference call.
Mr. Sneath, what is your recollection?
MR. SNEATH: That is right.
JUDGE ZIEGLER: Who will argue?
MR. POPPE: It will be a tag team affair. But I will start, if that is all right.
JUDGE ZIEGLER: Very good.
MR. JOHNSON: Do I get extra points because I have to go it alone?
JUDGE ZIEGLER: You can have extra people, not extra points.
MR. JOHNSON: No points. All right.
MR. POPPE: Actually, we will help you out.
MR. JOHNSON: Why am I sure I don't want that?
MR. POPPE: If you could bring up the

algorithm slides.

MR. ANTHONY: If we do run short, would it be okay to rely on the brief?

JUDGE ZIEGLER: Of course.

If you need a few extra minutes, it will be granted.

MR. POPPE: Your Honor, we are not going to attempt to address every single claim term.

Many of them we think are adequately covered by the briefs.

We are going to --

JUDGE ZIEGLER: I agree.

MR. POPPE: We will focus on some particular terms, where we think additional elucidation would be helpful.

JUDGE ZIEGLER: Okay.

MR. POPPE: I will start by addressing a topic that is sort of an overarching topic.

It relates or it has implications for really every single claim that has been asserted in this case in both patents.

And it is the topic that you have already been sort of previewed about.

Namely algorithms and how means plus function terms must be interpreted, when

identifying the corresponding structure in a software related claim.

I am a little stuffed up.

So if you have trouble understanding me, let me know.

I will repeat myself.

So the parties agree that there are algorithms that are the focus or part of the focus of each of these claims.

The parties agree there is at least one means plus function term in each of those claims that corresponds to an algorithm, and for which the corresponding structure is an algorithm.

And the dispute between the parties really is not about whether there is an algorithm at all.

But the extent and the degree of specificity with which the algorithm must be identified for purposes of identifying that corresponding structure.

So the first case that kind of addressed this topic generally was WMS Gaming.

It was a federal circuit case that held generally that when a means plus function term relates to software, that the corresponding

structure is a process or computer chip programmed to perform the algorithm described in the patent.

However, there really wasn't very much of a description of the algorithm in the patent at issue in this case, so the court didn't have occasion to address the specificity issue we have here.

However, there have been subsequent cases that shed light on the analysis that is appropriate.

One of those is a case that has really broad application.

This isn't specific to software cases. But it has application to software cases.

It is the rule stated, for example, in default proof credit card systems. Federal circuit case from 2005. That corresponding structure must include all structure that actually performs the recited function.

Now, when you apply this principle to the software arena, we have several cases that apply.

In applying those, this is how we see the differentiation between the parties' position.

We believe Varian has followed the

principle enunciated in default proof credit card systems by identifying all the structure needed to perform the stated functions.

We have done that by identifying the entire corresponding algorithm, as identified in the specification of the patents.

Whereas, the University of Pittsburgh has not done that.

They have ignored large parts of the algorithm in favor of advocating for broad labels to characterize each of these algorithms.

And as we are going to talk about some more, we believe case law does not permit the University of Pittsburgh's approach but rather favors Varian's.

So let's turn to some of these cases now.

One is a district of Minnesota case from 2001.

And this has particular applicability here because of the nature of the disclosure of the patents in our case.

And what this district court case said in Itron was the corresponding structure in software means plus function case consists of, quote, "The particular flow charts disclosed in the patent."

And this is applicable here, because as you have seen, each of the patents has multiple flow charts that describe the algorithms.

And those are the flow charts that identify the structure corresponding to the related functions and means plus function terms.

This next slide identifies a couple other cases that have discussed what a corresponding structure is. In the context of a software patent. And a software means plus function claim.

The Network Caching case from northern district of California in 2002 said that the court must identify the specific routine.

Similarly, the federal circuit Tehrani versus Hamilton medical in 2003 said the court must identify the precise algorithm.

So there is a theme in these cases that you don't resort to broad generalities in identifying the algorithm from purposes of a means plus function claim.

You are supposed to be specific.

And precise.

The University of Pittsburgh has relied on a couple of cases in support of its position they

would like to discuss in a bit of detail.

One is Harris Corporation versus Ericcson, Inc.

A federal circuit case from 2005.

The University of Pittsburgh has cited this case for the proposition that in fact, the federal circuit blesses the idea of giving a broader description to an algorithm when identifying the corresponding structure.

And this is the language from that case, that they have cited.

And it says, "We hold that the corresponding structure for the time domain processing means is a microprocessor programmed to carry out a two-step algorithm in which the processor calculates first generally nondiscrete estimates and then selects the discrete value closest to each estimate."

What the University of Pittsburgh has said is, "Well, the patent in this case disclosed that time domain processing means algorithm in much greater detail than is described here."

So this case is blessing the idea of ignoring large parts of the algorithm and simply giving it a characterization.

But what the University of Pittsburgh has ignored is the very next sentence in this case.

I will show that to you now.

The very next sentence said, "Specifically, the patent discloses, as corresponding structure, a processor 37," which was referring to a specific processor identified in one of the patent figures, "advantageously comprised of a pair of processors," which include a support processor 37A, and a fast array processor 37B shown in figure 4, et cetera.

"Which is programmed to carry out the disclosed data recovery algorithm illustrated in several figures and described in several portions of text."

What this shows the court did not stop with a broad general characterization.

But it went forward and said the corresponding structure is the entirety of the figures and text describing the algorithm.

Another case they would like to discuss is called Odetics versus Storage Tech Corp.

This is not an algorithm case, per se.

But the University of Pittsburgh has claimed that it sets forth a principle that has

application here.

And the principle they quoted reads as follows.

"The individual components, if any, of an overall structure that corresponds to the claimed function are not claim limitations.

"Rather the claim limitation is the overall structure corresponding to the claimed function."

University of Pittsburgh has cited this case to say because the individual portions of the structure are not claim limitations, you can ignore them.

You don't need to identify them as part of the corresponding structure.

But that is not what this case holds.

We argued very briefly in our opposition brief that this is a principle that applies to the determination of infringement, not to claim construction.

And I don't think that principle or that argument necessarily -- the import of that is self evident.

So I would like to go in to more detail to explain what our position is on this.

There is a principle in determining

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infringement called the all elements rule.
What that says is when a patent claim has multiple elements, in order for an accused device to infringe, it must have each of those elements.
Either literally or by equivalence.
So I just made up a claim here.
Let's say you had a claim for an apparatus for catching fish comprising a rod, a reeling means, and a hook on the end of the line.
Under this all elements rule, in order for an accused device to infringe this claim, it would have to have each of those elements. Either literally or by equivalence.
It is not sufficient to say that the overall accused device is equivalent to this overall claim.
If it has a rod and a hook but no reeling means, either directly or by equivalence, it can not infringe even if one might think that the device as a whole was equivalent to this claim device.
Let's go to the next slide.
In my hypothetical claim here, I have intentionally had one of the elements be a means plus function element. Namely the reeling means.

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So let's suppose that the specification for this reeling means disclosed several structural elements. Namely a housing, a plurality of gears and a handle.
What the Odetics case would say in this case is that to infringe, you still only need to show that the accused device has a rod, a reeling means, generally, and a hook on the end of the line, in order to infringe.
When you look at those structural elements, it may be that the accused device does not have a housing, either directly or by equivalence.
Nevertheless, if the accused device has a reeling means, generally that is equivalent to that reeling means in the claim generally, it can infringe.
The all elements rule does not apply to the structural components of the means plus function element.
That doesn't mean that when identifying the corresponding structure you don't still have to identify those structural elements.
It is particularly important that you do so, so that you can perform a meaningful evaluation of whether there is infringement by

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equivalence.
And this is a requirement of that rule we discussed earlier, that you have to, by federal circuit precedent, identify all of the corresponding structure disclosed in the specification.
So let's proceed.
This is shown even more directly, when you look at other parts of the Odetics opinion. **A** prior decision in the same case by the federal circuit had addressed the claim construction issue.
And that process was summarized in this Odetics opinion.
And it described the means plus function term that was of particular relevance here. Which was rotary means.
And there is a design of the rotary means in the figure on the right, which came from the patent.
And the federal circuit in Odetics described the claim construction ruling from earlier.
This court held the structure corresponding to the rotary means element was the components

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that received the force and rotate as a result of that force.
I.e., the rod, gear and rotary loading and loading mechanisms.
In other words, the same court that made the statement that the University of Pittsburgh is relying on, when earlier identifying the structural components of that rotary means, did not simply give an overall broad label to the means, but went through and identified each individual structural element.
So this is what we mean, when we say that the claim construction ruling and the infringement ruling are two completely different things.
And the statement that the plaintiff is relying on here applies only to infringement and namely the way that the all elements rule applies to a means plus function claim.
And not to the separate claim construction process of identifying the corresponding structure.
And one last point on Odetics, there was a description in the federal circuit case talking about the district court's mistake. What

happened in Odetics is that after the claim construction ruling by the federal circuit, the court remanded to the district court to reconsider the question of infringement.

What the district court said was that there was no infringement, because one of the structural components that had been identified as part of the corresponding structure, namely a gear, had no corresponding element either directly or by equivalence in the accused device.

And so now we get back to this statement that the University of Pittsburgh is relying on.

They said, "No, that doesn't matter. You don't have to have had that particular structural component."

Because that is not a claim element.

You look at the overall rotary means to determine whether it is the equivalent of the allegedly corresponding component in the accused device.

So that is what was going on.

The court was not saying that the gear was not part of the corresponding structure.

Simply, you didn't -- it wasn't appropriate to look at that level of detail in the

infringement analysis.

So I would now like to explain how this applies in the context of one of the particular patent claims -- actually, two of the claims in this case.

The tracking means of '431 patent claim 21.

And the processing means of '431 patent claim 26.

I am not going to go in to this in much detail, because you heard abundant testimony on this.

But here we draw together a couple of the principles that we just described.

There is the default proof credit card principle that the corresponding structure must include all structure that actually performs the recited function.

And the Itron principle, that the corresponding structure consists of the particular flow charts disclosed in the patent.

And you heard testimony from Dr. Balter, where he identified the steps and the flow charts in the patent, that constitute the corresponding structure for these two means claims.

And in fact, during the rebuttal testimony

of Dr. Schell, you heard him say that those flow charts were necessary for the performance of the functions.

His additional testimony was that there are other algorithms that can be used to achieve the same goals.

But that is not an appropriate consideration in claim construction.

That might come up, when you are addressing whether a particular algorithm is the equivalent of the algorithms disclosed in the patents.

And you can -- you might argue in that instance that while this algorithm may not have every single individual element disclosed in the flow charts of the patent, but on the whole, it is equivalent.

But you still need to identify all of those individual elements as the corresponding structure, so you can properly analyze whether in fact the accused algorithm is the equivalent or not.

There is also another important point that applies here in the context of interpreting the tracking means and processing means of the '431 patent.

In the specification of the patent, there are several statements that talk about how components of the algorithm are part of the invention.

Not part of an embodiment of the invention.

But part of the invention itself.

And so some particular examples of this -- well, these are the three examples that are in the specification.

One says an important part of the invention is that robust motion flow is used to perform the fine alignment.

Another statement is that the robust motion is represented by data points called inliers, Dr. Balter testified about this.

And in the present invention, the data points are the pixel values.

So again, this is saying this part of the algorithm is something that is in the invention.

Not just an embodiment.

And then finally, a statement that in accordance with the invention, I think that is a sigma, is lowered depending on the largest error in the motion flow parameters.

The exact meaning of that statement isn't

important.
What is important is this step in the algorithm is described as part of the invention.
And in our brief we cited several cases that say that when you have an element that is described in the specification as a part of the invention, that you can't ignore that element.
You can't just read it out of the invention.
In fact, the Harris Corp. case that we talked about a moment ago, that the plaintiff cited in their brief applies that very principle.
And there are many, many other cases that support this holding.
Like I said, we cited a couple of those in our brief.
So these details of the fine alignment process, as an example cannot be read out of the algorithm.
You can't just simply say fine alignment alone is the algorithm.
Because the specification says that the details are an important part of the invention.
I would next like to discuss portal image.
So now I am moving away from the algorithm

issue.
You heard testimony from both Dr. Balter and Dr. Schell about what a portal image is.
And Dr. Balter explained that it is an image created with a megavolt treatment beam.
And also that the resulting image is two dimensional.
And I am not going to go through detail about our argument on this.
A lot of it was presented during the direct testimony.
And again, in our brief.
But I did want to point out a couple things.
One is that the University of Pittsburgh's proposal for the interpretation of this term ignores its own expert's explanation of what a portal image is.
You heard Dr. Schell testify both on direct and on cross examination, that a portal image must mimic the treatment beam.
He didn't agree that you have to mimic it in terms of the energy of the beam. But he did admit that it must include the beam shape and the beam angle.

And that is not reflected in the plaintiff's interpretation of portal image.
And these are key elements.
And it is reflected in the portion of Varian's proposed construction, that says that it is the treatment beam that is generating this portal image.
I would next like to talk about an element in claim 26 of the '431 patent regarding which there is also a dispute of interpretation.
Claim 26, as you will recall, is not the tracking claim.
It is a broader matching claim.
It says -- broader in one sense.
Broader in that you don't have successive images.
But narrower in the sense it explicitly calls out that when you are doing matching, you do it without input of any physical dimensions of any features in the images.
So there is a question about what this means.
And what we pointed out in our brief is that during the prosecution history of this claim, there was a point in time at which the

patent office had said we are going to allow this patent to issue.
But before the patent actually issued, the attorney for the applicants came forward and said, "We found a new prior art reference that we think anticipates one of the claims in our patent."
That reference was by an author called McParland.
And the attorney said claim 1 of our patent we think is not patentable over this reference.
So we are going to amend that reference.
And in the process of doing that, they also presented argument about why certain of their other claims did not need to be amended.
And were patentable over McParland.
Now, when they got to claim 26, something interesting happened.
They referred to this phrase about not inputting physical dimensions.
But they changed the wording of it in a significant way.
They did not say without input of any physical dimensions of any features in the images.

They said without input of any physical dimensions or any features in the images.

Which broadens the statement in a material way.

It is saying we can do matching without inputting physical dimensions.

And now in addition to that, we can do matching without input of any teacher in these images.

Now, the plaintiff has said that was just a typographical error. No harm done.

But that is wrong for two reasons.

First of all, it is not a subjective test, when you are determining what the prosecution means and how it relates to the interpretation of a claim.

If a person of ordinary skill in the art would read the statement and think that it was being done intentionally and materially, then it has an impact regardless of what the prosecutor's intent was.

But more importantly, the indication is that this was not a typographical error at all.

Because the placement of "or" instead of "of" was material and necessary to the

applicant's argument about why McParland did not render claim 26 unpatentable.

To understand this, let's first take a look at the original claim 1, that the applicants did say was not patentable over McParland.

Claim 1 included the following elements.

A means digitizing a portal image and a simulation image.

Which is essentially the same digitizing means that is in claim 26.

And it had a processing means, processing the digital image signals to generate match signals, which is essentially the same processing means as in claim 26, merely without the additional statement about without input of physical dimensions of features.

And then finally there was an output means, which is essentially the same thing as the display means in claim 26.

So a claim that was the same as claim 26, except for the statement about without input was admitted by the applicants to be not patentable over McParland.

This is borne out by their discussion of claim 26.

When they were explaining, as I said about claim 26 to the examiner, the only basis why they said that claim 26 was patentable over McParland was that claim 26 required this additional step of without input of physical dimensions of any features. I am sorry, or any features.

So now that we focus on that particular element, let's look both at what the examiner said about McParland and about what McParland says about itself.

In characterizing McParland to the examiner, the applicant said McParland specifically requires the user identify anatomical match points in the two images to even begin to perform an alignment.

And looking at a statement from McParland that talks about the same process. It says images are displayed on a monochrome monitor and registration match points are selected using a cursor and mouse interface.

So what is happening here is not that the user is inputting dimensions of any features in the image.

Rather, the user is simply marking features in the image.

So if you were to say, "Oh, but in the claim 26, we require input of physical dimensions," well, that wouldn't help you distinguish McParland, because it didn't require physical dimensions either.

They had to go broader than that.

And argue that their patent didn't require physical dimensions or any features to be input.

And that was the only way that they were able to get around McParland.

And there is another statement in the prosecution history, which reflects this, where they said the claimed apparatus does not require identification of any information in the images. Such as the anatomical match points required by McParland.

Now, that statement wasn't made specifically in regard to claim 26.

It was related to a different claim in the patent.

But the characterization of McParland is the same.

It doesn't rely upon which claim is being discussed.

So unless you have any questions, I have no

further discussion on those points. And I will turn the discussion over to Mr. Anthony.
MR. ANTHONY: What is the order of terms?
MR. POPPE: You will be discussing the digitizing means and the '431 patent.
MR. ANTHONY: Thank you.
So your Honor, in the '431 patent, and of course the '431 patent is the image matching patent matching two x-ray images, a poor and a good one.
And the claim term is digitizing means.
And it says for digitizing successive portal images to generate successive sets of digital portal images signals.
So the function is there.
And it is in the claim.
The issue is: Is there structure?
As Mr. Poppe has said, that whenever means is used, there is an assumption it is a means plus function claim, as authorized in 35 USC 112, paragraph 6.
And so here the use of the means creates the assumption that this is a means plus function claim.
And we have to consider not only the

function but the structure that accomplishes that function.
And so figure 1 is the sole drawing or image that shows the digitizer.
And that is element No. 29.
It is a box.
It is a box labeled digitizer.
It does not embody any circuitry, hardware, optics or anything for digitizing.
It just says it is a digitizer.
And as the witness has testified, that the word digitizer appears in the specification in one spot only.
And that is column 4, lines 53 through 59.
And it has somewhat of a circular definition.
A digitizer is something that digitizes.
That of course really conveys no structure.
The witnesses are in agreement, there is a wide variety of digitizers.
And you heard Dr. Schell say that well, it is not just one digitizer, because you need more than one digitizer here.
And there is no information either in that sole box in figure 1 or here in column 4 that

tells you what each of those two digitizers are. And Dr. Schell certainly agreed with that in his testimony today.
And this is the default proof credit card system.
Had a very similar limitation. It says means for dispensing at least one debit card for each transaction.
And so a bare bones statement similar to the statement in the '431 patent followed by a statement in the specification that said the dispenser 40 is loaded with three or more stacks of debit cards.
Now, here the federal circuit at 412 fed third, 1291, 2005, held that the patent failed to identify adequate structure corresponding to the means for dispensing.
And found that therefore dispenser was not supported by structure.
What is important about this, your Honor, is the purpose of 112-6. And efforts of this nature to defeat the purpose of 112-6. Supreme court says if you have a broad, all encompassing claim, you can't have a claim that any way you digitize an image.

Just like you can't have a claim to any way you dispense a card, because that is unduly broad.
You will thwart innovation by taking up all that territory with your claim.
So when the 52 act was passed, they said "Okay, we are going to take care of that problem" by requiring the applicant, the patentee to specify particular structure that represents that means.
Then we will limit him to that structure and equivalence thereof.
Now, how do you defeat that?
Don't put any structure in your patent.
You defeated the purpose of 112-6 in curing the Supreme Court's objection to broad means claims.
This is a back door way of undoing 35 USC 112-6, simply don't put any structure in. Now you have no gauge for equivalence. And in the infringement case, you will hear them argue, everything is equivalent. You heard some of that today.
That is contrary to the very purpose of 112-6 you must have structure.

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Now, here -- let's go to the next slide.

Here there is actually something different than the federal circuit case. In fact, highly unusual.

There is a reason why there is no structure for the digitizer in the '431 patent, and that reason is selfishness.

What happens, and we have the testimony of Mr. Athanassiou, and we have his transcript here. Mr. Athanassiou was the designer of this system.

And he had a special connection with the company that was building the digital camera, which embodied the digitizer.

And he found out a way to vastly improve that digitizer.

Vastly improve the digitizer on the marketplace.

So what did they do?

They decided instead of disclosing the structure in the patent, to withhold it as a trade secret, make it proprietary to U Pitt and CMU.

And indeed, when I got to that point, I said "Mr. Athanassiou, what is the digitizer

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structure you actually use?"

He said, "I will not tell you that. That is confidential."

We had to go on a confidential record before he would reveal what changes he made to the commercial digitizer to vastly improve it for the purposes of this patent, and particularly to have it operate at the speed that was necessary for this tracking function.

And so here there is a selfish reason why the structure is not there.

Not only a selfish reason, but of course we defeat 112-6 by having no structure to point to, so that we can't do an equivalence consideration in determining infringement.

So here we would like holding from this court that there is no structure disclosed.

Matt.

MR. POPPE: Now talk about tracking and successive.

MR. ANTHONY: Tracking.

There was some suggestion from Dr. Schell, that can you track by taking an image on one day during one treatment and perhaps a day later, perhaps hours later, perhaps days later you take

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another image and compare those two, and you tracked movement.

Well, sometimes common sense needs to come in to play.

Tracking here is all about a very dangerous radiation beam that kills cells.

Yes, it kills tumor cells, cancer cells, but also kills healthy cells.

And we want to track in order to limit as Dr. Greenberger said, limit the damage to healthy cells.

How do we track with images, which are taken at vastly different times?

And so tracking requires rapid taking of images in order to determine movement.

And then doing something about it.

This was the point that the witness said that tracking has two components.

One is determining that movement has occurred.

That is the tracking.

And secondly, doing something.

Tracking is not losing sight of something. It is following it.

So something in the equipment must follow

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it.

So in our suggested construction, we say the function of tracking is automatically adjusting radiotherapy diagnostic equipment such as switching the radiation beam on or off or repositioning the patient couch.

Now, our supports for that includes intrinsic evidence.

Go to the next slide.

You can see that a column 9, lines 14 through 16 is that express statement.

As tracking continues, successive portal images are matched with the next proceeding portal image, not well spaced apart in time or images, to generate the updated transform.

And if we go even to the language of the claim.

Look to the preamble of claim 21.

It is an apparatus for matching portal images to control radiotherapy diagnosis equipment.

So both the idea of measuring movement and doing something with that measurement is in the claim itself.

Figure 11 illustrates a tracking routine.

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I won't go through that now.
Because I think it was well handled by our witnesses.
And U Pitt of course argues the file history.
And it is a circular argument.
Patentee stated the tracking called for in claim 21 is effected by the movement detected in successive images generated by the single portal imager.
Effected.
And that of course means caused.
It is causation concept.
Something is effected by being changed.
And that is our construction, as you can see that, cause, paren brought about by the movement detected in successive images.
And so the language that is cited by U Pitt actually supports our view that there needs to be not only a detection of the motion.
But you have to change the equipment in response to that detection of motion.
And U Pitt argues that the matching does not require the determination of movement of features between images. But can be used for

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other purposes.
That is an incorrect argument.
And mere matching of images only gives you the information of movement.
And it does not take it the rest of the way to cause actual tracking.
And there is multiple purposes for tracking.
And of course in the patent, two purposes that are explained is turning the beam on and off and moving the treatment couch.
Thank you.
MR. POPPE: Your Honor, we will shift to the '554 patent now.
Unless you want to handle it differently.
JUDGE ZIEGLER: That is fine, sir.
MR. POPPE: I will discuss the first element, which is another one of the algorithmic elements.
Specifically, the means determining movement of said patient from claim 20 of the '554 patent.
Again, our expert, Dr. Jiang covered this in detail.
This slide simply illustrates how the

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principles I discussed earlier apply here in the same way they apply to the '431 patent.
You again have the statement from default proof credit card that the corresponding structure must include all structure that performs the recited function.
You have the Itron case, corresponding structure consists of the particular flow charts disclosed in the patent.
And you have Dr. Jiang's testimony regarding what those flow charts are as disclosed in the specification of the '554 patent.
It is therefore our position those flow charts and the related text and the specification constitute the corresponding structure for this means term.
If you will go to the next slide.
Just as in the '431 patent, the '554 patent also includes statements about how portions of this algorithm constitute the invention. Not simply an embodiment.
So for example, there is a statement that the invention satisfies certain requirements stated immediately beforehand by utilization of successive levels of filtering and templates,

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which are modified to accommodate for actual conditions.
So this incorporates that idea that was discussed at length about first template matching as an element of the algorithm.
And also the ability to adjust for varying lighting conditions.
For example, by changing the template to account for those varying lighting conditions.
And then secondly, you have a statement that an important aspect of the invention is the fine tuning of the tracking templates called for at 120 in figure 6.
Figure 10 illustrates the details of fine tuning the templates.
So this is saying that the fine tuning of the templates to account for varying lighting conditions is not just part of the invention.
It is an important aspect in the invention.
And yet, it is an aspect the plaintiff would like to read entirely out of the claim construction of this case.
And that is not appropriate under the principles we discussed.
Now I will turn argument to Zheng Liu to

discuss camera means and gating means.

MS. LIU: Your Honor, in '554 patent, the expert has already testified regarding what a camera means mean.

So I won't go in to too many details except a few of the issues that is raised by plaintiff.

So first is there is a presumption that a term with means in the language is a means plus function term.

It is the plaintiff's burden to overcome this assumption.

And the case law also clearly requires there has to be sufficient structure, not just some structure.

University of Pittsburgh has been arguing that there is some structure, for example the name camera.

Camera is a camera.

However, there are many different types of cameras available with vastly different level of capabilities.

Like our expert Dr. Jiang has testified.

In the majority of the cameras in 1996 are not even digital cameras and they cannot generate digital image signals.

The patented invention requires a camera that is sensitive at different lighting conditions.

And it processes images at high speed. So they can track the movement of the fiducial during breathing.

And it has to operate at high resolution.

And that requires special cameras.

And the patent did not disclose the structure of special cameras.

Except mentioning of a CCD.

In University of Pittsburgh's reply brief for claim construction, it raised an argument that Varian's proposed construction using the phrase one or more cameras contradicts with Varian's own legal argument.

But it does not.

So first, the word camera is too generic to constitute a sufficiently definite structure.

And when the specification does not disclose the structures for camera means, Varian cannot add to that.

Varian can only identify what is disclosed in the specification.

But cannot add to its proposed construction

what the specification does not have.

University of Pittsburgh also cited the word camera is in the sentence in the abstract of the '554 patent.

But the mere mention of the name camera still doesn't tell people what camera means is. What type of camera.

What type of capability it requires to meet the specific requirements of this patent.

As Dr. Jiang testified earlier, there are so many requirements, because the algorithm has to perform under various lighting conditions, and you have to be able to perform all of these tasks to be able to be the camera -- to meet requirements for camera means.

And the patent did not disclose the structure.

In addition, the patentee only envisioned visible light cameras.

The specification sets forth using natural fiducials such as scars or other prominent features of a patient.

It is well known that you -- natural fiducials such as scars can only be seen under visible light.

And the specification emphasizes the ambient room lighting conditions of the treatment room.

And as Dr. Jiang has testified, unless a special highly concentrated infrared light source is used, any reflection of background infrared light, such as the patient's body will emit some infrared light, a machine will emit some infrared light, these will -- may exist in the treatment room.

But these are too weak to be used for tracking.

Unless there is special light source and special fiducials, which neither of them is described in the patent.

Also, because the majority of the cameras -- like Dr. Schell has mentioned that infrared camera and light source were known in -- in the research community around 1996.

Even though they were known, they were not commonly used.

The majority of the cameras used are visible light cameras.

So the public knows the requirement of patent claims would demand specific disclosure of

any unusual structure.
And the patent never mentioned the word "infrared" or any other light spectrum. It just generally refers to light.
And when most of the cameras are visible light cameras, when the specific algorithm or design to deal with this situation, the camera has to be limited to visible light cameras.
Again, the special algorithms were designed to monitor the fiducials under varying lighting conditions as Dr. Jiang testified.
The varying lighting conditions is common in the treatment room, because people -- the different level of the lights available.
I won't go in to all these details for the citations.
Basically, there is plenty of evidence in the specification showing that the algorithms were specially designed to meet -- to overcome this problem.
And it is an important part of the invention.
In University of Pittsburgh's reply brief, it also -- let me go back.
Plaintiff initially argued that the patent

examiner equated the camera means of claim 20 with infrared camera in the cited prior art reference.
It is a Gerig patent.
And Varian countered that the examiner did not characterize Gerig's camera as infrared camera.
It only just mentioned it.
And then in the reply brief, plaintiff has a new approach.
However, this does not really change the prosecution history.
The examiner applied the camera means in Gerig for the purpose of 103, obvious rejection. Not section 102, anticipation rejection.
We all know 102, anticipation, you are basically saying something in the prior art and something you are trying to claim, they have an element by element match.
But for 103, there is no such indication.
The examiner basically was saying that, oh, there is a Gerig reference.
And Gerig reference in light of another reference make the claim obvious.
And that does not mean that examiner equate

the camera means claim 20 to Gerig exactly.
It is just saying it is obvious.
In addition, the examiner never stated that camera means includes infrared cameras.
Actually, the word "infrared" did not even appear in that office action.
More interestingly, in the response to this office action, this particular office action is Exhibit 7 of plaintiff's opening brief.
And this office action rejected more than claim 20 and many other claims.
And the patentee differentiated from the Gerig patent on the basis that Gerig uses infrared light, infrared cameras.
And it is basically saying we don't use that.
Of course, that is claim 1.
Not claim 19. And later which becomes claim 20.
However, claim 1 is a claim that is very similar to claim 20, currently.
Also the specification has only described the one camera.
Not different.
The specification only describes one

camera, one type of camera.
And if the claim 1 was able to survive, by distinguishing on the basis that Gerig uses infrared light and they do not, there is a strong indication that infrared light is not included for claim 20.
Another phrase still in dispute is gating means generating gating signals synchronized with said movement associated with breathing by said patient.
And the parties disagree on the corresponding structure.
Varian believes that because the specification very specifically described the first specific tolerance range.
The second specific tolerance range.
And that should be included as part of the structure.
And the plaintiff disagrees.
The two tier tolerance structure is a key part of the invention.
You can see that in many different quotes throughout the patent.
They are in summary of the invention.
In the brief description of the preferred

embodiment.
It is everywhere it talks about using the alarms.
Having the two tier structure.
And this first paragraph, long paragraph, Dr. Jiang also identified.
Specifically talks about display includes a traffic light 67 heavy in green section. Then there is yellow section, red section.
And also there are other descriptions in other parts of the patent.
In University of Pittsburgh's reply brief, it had a new argument saying that Varian's construction contrasts contradicts with Varian's own publication about the meaning of gating signals.
But this argument is not relevant.
A Varian publication from 2005 is not proper extrinsic evidence for claim construction purposes.
It has incorrect timing, thus is not relevant to what a person of ordinary skill in the art would have thought at the time of the patent application.
And also the claim construction has nothing

to do with how defendant may refer to a term under different circumstances, but what the patentee intended the term to mean in the patent at the time of the application.
So we believe this University of Pittsburgh, this argument, is not relevant.
Thank you, your Honor.
JUDGE ZIEGLER: Anything further?
MR. POPPE: Yes.
Mr. Anthony will address two more terms related to the '554 patent.
One is the claim 20, digital image signals representative of an image of the patient. Then in claim 21, the term fiducial on said patient.
JUDGE ZIEGLER: Counselor, according to my calculation, you have completed the time allotted.
I will give you an extra ten minutes.
MR. POPPE: We will reserve that time, your Honor.
JUDGE ZIEGLER: The court reporter needs a break.
We will take a five minute recess.
(Recess taken.)
MR. JOHNSON: There are some points that

really need to be emphasized.
JUDGE ZIEGLER: You may do so.
MR. JOHNSON: So let's talk about this camera means in the '554.
We assert that it is not a claim that needs to be construed because it is clearly understood.
Varian says they define it as generating digital image signals representative of an image of the patient.
That is found nowhere in the patent.
And we have already shown you numerous references where they only talk about a camera. So what did we get in response, since we know this is a means plus function or at least they say it is.
Then they say it is too generic to be structured.
Well, the fact of the matter is, if a claim element contains the word "means" and recites a function, it is presumed, however, if the claim recites sufficient structure to perform the claim function, it is not means plus function.
You had me cross examine their witnesses. They testified of course there were cameras out

there that could do this.
I got in to a quibbling match over whether or not there was one appropriate lens or another. But that to the one of ordinary skill in the art, which is the standard, not what we heard today.
The standard is what would this mean to somebody of ordinary skill in the art?
They all testified that yes, they understood what it was.
And yes, there were cameras available that would accommodate this particular result.
So to tell you that there were cameras that wouldn't doesn't answer your question.
We provided you with evidence, which demonstrates that the camera in this circumstance is what it is.
I would also like to comment on those slides about the statement that in 1996 there were no digital cameras, and they couldn't do this.
There was no evidence of that put in this record.
Nor could they, because it is simply not the case.

So I will skip through this.
But I want to go to Dayco.
That is about adding limitations to claims not required by the claim terms themselves is impermissible.
What we have seen and heard today is an attempt to add claim terms.
Now, you just heard that Gerig somehow was distinguished on the grounds we distinguished Gerig on the grounds it was infrared camera.
You can look at the language. We will give it to you.
That is not true.
At no point did we assert that the fact that Gerig is an infrared camera in and of itself meant that that was a distinguishing characteristic.
Gerig was distinguished on other grounds.
Specifically, speed and other ways in which it operated.
Our response was Gerig as mentioned can only determine patient position at a repetition rate of five seconds.
Obviously, too slow to detect breathing.
Furthermore, there is nothing in Gerig to suggest

how the rhythmic movement associated with breathing could be extracted from a camera image.
That is at 9 and 10, Bates stamp 127444.
So the assertion that we attempted to distinguish Gerig on the ground we didn't have infrared is wrong.
Now, I will skip to the rest -- the next point they had was this question about digitizer.
And what we did, we cite you to a case where the word "detector" was used.
In this case, personalized media communications.
Here is -- the following was stated. "The fact that a detector was defined in terms of its function does not detract from the definitiveness of structure.
"Even though the term detector does not specifically evoke a particular structure, it does convey to one knowledgeable in the art a variety of structures known as detectors."
If you substitute the word "digitizer" for "detector", that is the -- it would convey to one of knowledgeable skill in the art, that you would use a digitizer.
Because it was well known and understood.

Now, here is our construction of these digital image signals representative of an image of said patient.
We literally use the plain meaning.
We only substitute the word "likeness" for "image".
Although it doesn't matter.
What does Varian do?
It says digital images, signals that collectively represent a single two dimensional image of the body of the person undergoing radiation therapy.
That is not claim construction.
That is claim rewriting.
They are simply adding language that doesn't exist in any of the claims to try to get as narrow a reading as possible.
Because we are going to be able to demonstrate at trial they infringe.
Now, the next point has to do with the fiducials.
We say the digital image signals may include fiducial markers on the patient.
And the court heard about the fiducials. You are aware that these fiducials are used in

the operation of this particular device.
But the specification says as shown in figure 5, the display 53 presents an image of the patient 37 with the fiducials appearing prominently.
Clearly, they are being used as part of the invention.
What happens as far as we are concerned is you can use either natural or artificial fiducials.
How do we know that? It says so right in the specification.
I didn't hear anything about that primarily, because their witness gave it away on cross examination.
But one of the problems they were making was that only natural fiducials could be used, not artificial.
I assume it was abandoned since it wasn't argued today.
But I want to emphasize that point, because it is consistent with other things we heard today.
And finally, all of the discussion about what the invention was, you notice there was no

tying it directly to the claim.
Because they are dependent claims that cover specific implementations.
Claim 21, for example, an image of at least one fiducial.
And that indicates that there can be other scenarios, where there could be more than one fiducial.
Different types of fiducials.
But the point is that it is not proper to try to rewrite a claim by asserting it can only mean a certain thing.
And that is exactly what they have done here.
Now, this means determining movement, we say determining movement of the patient directly or indirectly from the digital image signals.
And we added for completeness, including movement associated with breathing by the patient.
Because that is what the claim says.
And all that is required is a processor programmed to implement a patient motion detector and equivalents.
What does Varian say? Determining movement

of the patient from the digital image signals of the patient's body including movement associated with breathing by the patient, which is fine.
But then they say it is a computer processor programmed to perform the specific software routines set forth in attachment 1 hereto.
In other words, you heard the argument. Again, that that means that everything in the algorithm has to be part of the claim.
Well, they then go on to argue that these digital image signals, the artificial fiducials are required to be of the patient's body or on the patient's body, which means that you can't have an artificial fiducial.
Now, let's look at the intrinsic evidence. That is the evidence in the patent and specification on means determining movement.
You can see listed here numerous instances where the patient motion detector 47 detects and identifies the fiducials and then tracks their movement.
Go down to the bottom.
The invention is directed to apparatus responsive to movement of a patient which

identifies and tracks movement.
Tracking movement is not ambiguous.
It is plain.
And therefore, in order for them to import language or to use prior art, they had to prove to you that there was ambiguity about this language.
They didn't do that.
What they really did was make an argument about invalidity.
And this is not the time or the place for invalidity arguments.
I will be more than happy to address those arguments and the fact that the prior art they claim is prior is not at another point in time.
For your purposes, as we pointed out today, the question is you don't look at prior art unless there is an ambiguity.
And you don't address validity, as I pointed out earlier this morning, unless there is the ambiguity, which causes you to need to use this effectively little used operation of evaluating validity, reading of claim to avoid validity.
The reason they had to do it was they have

difficulty with the plain language.
Now, you heard about WMS Gaming.
I was interested in that analysis. In large part because the way he argues it, it would appear that oh, that meant that everything was included.
But if you look at that structure, where they had the particular means.
And they described it.
It didn't say you had to have each of the elements internally.
He admitted that with his reel.
What did it have to do? It had to perform the operation.
That is what is patented.
The operation of doing the reeling.
And he glossed over that, because if you perform the operation, and you can do it, let's say you have a reel that has a red housing or a reel with no housing, and a reel with green housing, still a reel.
It performs the operation of reeling.
Now, here is our patient motion detector algorithm.
You heard the testimony about Varian limits

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this to requiring at least 30 steps.
Then it says Odetics doesn't say anything different.
And they try to distinguish Harris versus Ericcson.
But if you notice the distinction of Harris -- of the Harris case, they didn't point out the fact that the court stated that a microprocessor programmed to carry out a two-step algorithm in which the processor calculates generally nondiscrete estimates and then selects a discrete value closest to each estimate is the construed claim.
It is true you have to look at the rest of the algorithm for purposes of seeing if there is structure there.
But the construction, which is what we are doing here today, is exactly as we show it.
And therein lies the rub.
Because if it is described as a two step algorithm that performs these estimates, if you have a two-step algorithm that performs the estimates to arrive at the result, you are going to infringe.
And there is a reason, your Honor,

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logically.
It is because if you look at any of those flow charts and even the ones in our patent, they have correcting techniques.
Like if this happens and this is false, then you go over here.
But if it does happen and you skip all the way to the bottom, those correcting techniques while they are useful for purposes of making sure that the operation works, not required.
If you could do it perfectly every time, you could skip and you wouldn't need any of those correcting techniques.
But that is what is contained in the algorithm, because that is the way you would write a particular flow chart.
It doesn't matter if you check it step A or step C.
What matters, you accurately get the result, which is to track a fiducial or to track the movement.
If you look at the Phillips decision, where it says other claims of the patent in question, both asserted and unasserted can be valuable sources of enlightenment as to the meaning of a

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claim term.
Differences among claims can also be a useful guide in understanding the meaning of particular claim terms.
We put that in because we have numerous dependent claims that cover very specific aspects of the invention.
And they ignore that, because they want to say oh, you have to have this aspect of the invention. Well, it is claimed in a dependent claim. That is all we have to do. No more was required.
This gating means. We just talked about it.
Our definition is on the left.
Generate gating signals synchronized with the movement and the structure is the computer programmed to implement a gating signal generator.
What is a gating signal?
It turns the beam on and off. It actuates the beam.
That is what it does.
You can turn the beam on and off on a variety of circumstances.

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But look what Varian did.
Varian said you had to be a computer processor programmed to perform the following specific software routines.
The fiducials move outside first specified tolerance range.
Then you have to display alarm warnings.
Then the fiducials have to move outside a second specified tolerance range, generate and transmit signals to the connected equipment to turn the radiation beams off.
Then if they move back within, you can turn it on again.
Guess what?
That is nowhere in the patent.
In fact, that combines two different claims.
One covering alarm warnings.
The other covering the gating signal.
There is no excuse other than by adding as much detail as you can, you can try to avoid infringement.
The intrinsic evidence, we cited it in the patent.
But it is very clear, your gating signal

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generator has to send a signal to the beam generator and says activate, turn on or off.

And no more is required.

And you can see that in the detail. We will give you a book. I won't bother to read all this now. It is all there.

It is very clear that that is what it is doing. Anyone of ordinary skill in the art understands that.

Here is more evidence of what it is.

But I was amused by counsel's assertion that using a Varian publication for gating means is irrelevant.

Especially since their publication says gating enables a radiation beam to selectively treat a moving target by electronically turning the beam on and off at specified intervals.

Well, our people would tell you they were saying the same thing back in the early '90s.

So this particular document in 2005 is nothing more than reflect what was known and is known.

And that definition is the one we are using.

And it is commonly understood by those of

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ordinary skill.

I will skip through the alarm warning. I think we have gone through that.

Now let's go over to processing.

Computer processor that implements a patient motion detector and a gating signal generator and equivalents.

Again, they now have processor -- their definition requires a computer processor (i.e., a chip). Whatever that is.

Programmed to perform the software routines associated with the means determining movement of the patient and the gating means.

Doesn't make any sense.

A computer processor by definition is a collection of silicon chips. To add a parenthetical would only confuse things further.

Our definition is clear and it is very straight forward.

Now we come to the digital image signals processed by a processor, which is computer 49.

Again, this issue with the chip.

I will skip right past that.

Now let's go to claim 21.

Fiducial.

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I only want to say the following.

First we heard that if it was an artificial fiducial, it wasn't part of the claim. That was in the brief.

Now it has to be attached to the body. That is not in the claim.

And I was confused by what it meant to be on the body, because since I wear glasses as does your Honor, when I have my glasses on and a picture is taken, is that an image of me? I think so.

If I take my glasses off, and the picture is taken, that is still an image of me.

So having my glasses on or having fiducials on or off, nothing whatsoever to do with whether or not it remains an image of me.

The patent clearly discloses the use of fiducials with the patient's anatomical structure.

And they operate as a marker.

That is all they do.

And there is no reason to go with their definition which is a feature or object detected by the means determining movement and used as a reference point.

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It is a marker.

There was no ambiguity.

Not one of their witnesses testified it was ambiguous in any way.

In fact, in their argument they certainly advocated that it was not ambiguous.

And again, this is a list of all of the fiducial -- all of the evidence referencing fiducial.

You will notice that the bottom, it is called the same thing in the dictionary, in the stereotactic radiotherapy dictionary.

And it is referred to that in various patents.

So I don't think there is any doubt but what one of ordinary skill in the art would call this a marker.

We have gone through this on said patient. It could be on the patient in a lot of different ways.

And not without having to be taped directly to the -- attached directly to the patient's body.

There is nothing in the patent that required that.

They then go on to say it has to be done without a rigid spatial relationship to other fiducials.

Nothing in the patent says that.

They want it, because it will help them with a noninfringement argument, I suppose.

But that is not what we are here today to do.

We are here to construe these claims as a matter of law.

We are limited to what the claims say.

And what the specification will support.

These are areas they didn't address. Means determining movement of at least one fiducial and means generating said gating signals synchronized to actuate said beam generator synchronism with patient breathing.

We request you adopt our analysis and the way we construed those particular claims.

Now let's go to the '431.

Again, I will move quickly.

This means digitizing successive portal images to generate successive sets of digital portal image signals.

As you can see on the left, we don't think

there is any reason to come up with any novel definition.

We identify digitizer of an electronic portal imager or digitizer for x-ray film and equivalents as appropriate structure.

They say there is no structure identified in the patent.

Well, the problem with that argument is their experts as well as ours all said digitizers are well known.

The argument was well, maybe there might be a digitizer or two that would not be useful.

Well, that is why these folks are of ordinary skill.

And the patent law is very clear.

You do not have to provide for structures, which are commonly known, any more detail than to put people on notice as to what they need.

And here is the case of Atmel versus Information Storage Devices.

All one needs to do is recite some structure corresponding to the means in the specification as the statute states, so that one can readily ascertain what the claim means and comply with the particulate requirement.

And that case had to do with a column that was located near a particular area on a chip.

And the only reason I know that is I litigated that case.

The fact of the matter is, that satisfies a particular area requirement.

And given the fact that everyone who testified here today understood what the structure is, there is no basis for arguing that digitizer should somehow not be construed by this court to be exactly what it is.

And here you will see what I just told you, that you don't have to include subject matter that is known in the field of the invention and is in the prior art for patents are written for persons experienced in the field of the invention.

Again, here is the situation involving the detector. I will not repeat the argument.

It has equal application here.

Again, we have also cited numerous references where they talk about this digitizing means, which generate a digitized image.

And just to be clear, all we are talking about is using a device that converts an analog

signal to a digital signal.

You have a cell phone with a camera on it, you have a device that will do exactly that.

Now we come to the word "successive".

I didn't hear much about successive today.

We take the normal dictionary definition, following in order.

They say taken in an uninterrupted sequence during a single radiation treatment.

There is nothing in the patent that says that successive has to be taken in an uninterrupted sequence during a single radiation treatment.

You heard the testimony of our expert, who said that you needed to have a reference frame and in successive pictures, so that you would be able to compare one of it with another.

But it wasn't limited by time.

Nor was it limited by one particular treatment.

Again, we gave the ordinary meaning to successive as following in order.

We think it is right.

And we disagree that adding the additional limitations that Varian has requested is proper

or permitted under the law.
Now let's go to portal image.
We said a portal image is an x-ray image taken by the treatment setup during the radiation treatment phase as opposed to the simulation phase.
We read that to you in the patent earlier today.
And we said a portal image may or may not be taken with x-rays of MV energy.
Now, what does Varian say?
They call it two dimensional image created by projecting a high energy megavolt x-ray treatment beam through the extreme portal and then through a patient at a particular point in time during radiotherapy treatment.
That is not in the claim.
The claim says a portal image is used.
It talks about the types of portal images there are.
And how they are accomplished.
And if they have a noninfringement argument based on a portal image, they ought to make it at that time.
They can't try to rig the process by

defining a term, which is explicitly stated set forth in the patent, in a way that would make it impossible for anybody to come within it.
Again, in our brief, we cite you to the intrinsic evidence which talks about the need for portal image.
And that defining them as x-ray images made by the radiation beam after it has passed through the patient.
And the point I want to emphasize here, your Honor, is by not having a specific energy requirement for the x-ray, it makes the most sense, because let's say it was 280 whatever.
And you came in at 200.
You say no, that is not a portal image, because it is only 200 and not 280.
In our view of the world, that is not how you read the claim.
If you are calling something a portal image, whatever voltage or dosage -- energy level you are using, it is still a portal image.
Our definition of port film is a radiograph x-ray taken on the radiation treatment machine.
No intrinsic and expensic evidence required.

There is nothing that says it has to be a specific range.
Only other point I want to emphasize. If there was something particular about the power or the energy setting, it would have been claimed.
And then the extraneous material added.
It has to be a two dimensional image. Why?
It is not required by the claim.
It has to have high energy megavolt x-ray treatment beam.
Not required by the claim.
And it has to go through the treatment portal.
And in through a patient at a particular point in time during radiotherapy treatment.
It doesn't.
Portal image is defined in a way that makes it clear.
They are adding limitations. And that is all they are doing.
Now we have the tracking means movement between successive sets of DPIS.
I have already gone through this.
The argument isn't going to change.

Again, in our brief, we have gone through this and showed you exactly where it is.
We have gone through the algorithm argument, your Honor, for the tracking means. I will not repeat it.
Except I want to emphasize two things.
You heard this argument about robust as being somehow critical to the patent. And somehow that made a difference in terms of how the claims should be interpreted.
And then you also heard the argument about well, different resolutions, and those are critical.
Well, dependent claims 22 through 24 relate directly to this robust motion flow.
So they are claimed separately.
And as we pointed out under the law, that is all that is required.
And this calculating repetitively different resolutions, that is dependent claim 25.
If they had wanted to limit their claims in other ways, they could have done so.
Because they demonstrated looking at just these claims, that they knew how to do.
Now, tracking movement, the only thing I

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want to point out here, take a look at their construction and ours.

We say determining movement by changes in the content of the digital portal image signals.

What do they say?

Automatically adjusting radiotherapy diagnosis equipment such as switching the radiation beam on or off or repositioning the patient couch, in response to patient movement.

That is about as narrow and limiting as you can possibly be. They have effectively rewritten the claim in a way that presumably makes them happy. But clearly is not proper claim construction.

And again, we showed you the intrinsic evidence.

The requiring the tracking movement to automatically adjust radiotherapy diagnosis equipment is simply not part of the claim.

It also would mean that every time we track, we have to adjust the equipment.

There is no reason for that to be true.

It is clearly not required by the patent.

Now we come to matching portal images.

We briefed this.

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Essentially, our argument is it is part of the preamble of claim 21.

And therefore is not a limitation.

Varian argues statistical now part of the limitation, you have to read in this additional work.

The problem is the law says that preamble claims are not limiting.

The only time you look to them is if they, quote, "Breathe life in to the claim".

And they didn't make any argument today because I don't think there was any to be made, about breathing life in to the meaning of the claim.

Because all the claim requires is tracking movement between successive digital portal images.

It doesn't require any of the rest.

We have gone through x-ray image.

But you see our definition.

An image represented on an x-ray film or captured by an x-ray image detector.

You see theirs, two dimensional, on and on and on.

We have gone through that.

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I think our definition is totally proper. And consistent with the patent claims.

Now we come to reference image.

The same thing.

We defined it before.

I am not going to repeat it here.

But again, you can see the difference between our definition -- our construction and theirs is we use the plain meaning.

They keep adding meanings.

Here again, this is the intrinsic evidence that supports our view of reference image.

And just the first one, reference images could be another x-ray image or another type of image.

It doesn't -- a requirement it be a megavoltage and done at a certain time and certain way is simply not part of the claim and not supported by anything in the specification.

Now, the processing means again, same arguments we made before.

Along with the issue of the corresponding structure.

We have already addressed that.

This is rather interesting.

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So let's -- this is the "of or" argument. They said because you said "or", when you were prosecuting your patent, that that somehow meant that you changed, except they neglected to tell you what the language in claim 26 is.

Claim 26 reads on the left, processing said first and second digital signals without input of any physical dimensions of any features within said images to generate matched digital image signals.

The only way they would be in a position to argue that that was something different, was if they could demonstrate that we had disclaimed some portion of the invention.

What he did, he found a word, he said oh, you said "or," not "of".

That couldn't be a typo. Because there were other things going on.

So it therefore follows that that really should be an "or".

If that were true, the patent office would have insisted that the word be changed.

It wasn't.

That is the claim.

And that is the claim they may not be happy

with.
But it is the claim that governs the issues in this case.
And the issue, the disclaimer, we briefed it.
But if they wanted to argue that it was a disclaimer, you would have to show explicit evidence, not argument, not speculation.
And that is all you heard today.
Now, the processing means and the algorithm, we have identified coarse and the fine alignment.
If you remember, I specifically asked their expert: Would somebody of ordinary skill understand coarse alignment?
The answer was yes.
Would they understand fine alignment? Yes.
Would they understand how to use algorithms to accomplish the result?
Yes.
Guess what?
That is what is required for purpose of providing disclosure to one of ordinary skill in the art.

Not only that, but if you look at the specification, you will see, for example, where it says the processing means includes coarse alignment means, which first affect the coarse alignment between the digital portal image signals and the digital simulation image signals.
And then following a coarse alignment a fine alignment is performed.
The fact of the matter is patent goes on to say if the coarse alignment is satisfactory, you don't need to do a fine alignment.
And here is that very point being made, column 6, 57 through 60.
You know under the argument advanced by the experts for Varian the fine alignment would have been required, because it was part of the algorithm.
I will not make the same argument we already made about Odetics and Harris, your Honor.
I will say that there were other district court cases, which we cited, which they didn't cite, which bear directly on this point.
Network Appliance, the court observed in applying this rule, WMS Gaming appeared to define

algorithm broadly, concluding a description of the steps necessary to carry out the claimed function was sufficient to constitute structure.
And then in the case in Minnesota, the court need not construe the individual components of the structures supporting the function of the means plus function element.
Instead, the court need only construe the overall structure which corresponds to those claimed functions.
And then here is the Phillips case.
Which we talked about in our opening.
I just want to emphasize one more time.
That your job is construe these claims.
And that in this case, unlike in Klein and other cases in which doctrine of construing claims to preserve their validity has been invoked, the claims terms at issue is not ambiguous.
It is not ambiguous.
You don't use this doctrine of trying to preserve validity.
And since nobody argued these claims were ambiguous, there is no basis for making a prior art argument they made here today, unless it is a

dry run for the trial.
And I thank them for that.
Without input of any physical dimensions, we say it means what it says.
They say using no information about the contents of the images other than information derived by the apparatus directly from the images themselves.
It is simply an overstatement of what is required.
And we recite all of the intrinsic evidence that supports our position.
And again, you see the argument about the one of ordinary skill.
I am not going to go through the display means, your Honor. It is pretty self evident it is a display is a display.
Nothing more is required.
And then we have the generating, again we use the term generating to mean bring into being.
They say actively processing a nondigital image to create.
It is not in the patent.
Not part of the claims, not part of the

specification.
Again, simply trying to come up with a definition, so they can have a noninfringement argument, that is not the purpose of claim construction.
So I will stop here.
Because I think we covered all of those terms that needed covered.
I wanted to thank you for your time and patience.
We will be providing you with a set of our slides, so you will have them to review later, if you wish.
Thank you, very much.
JUDGE ZIEGLER: Thank you, Mr. Johnson.
Mr. Anthony.
Mr. Poppe.
Ten minutes, sir.
MR. POPPE: Thank you, your Honor.
First, I want to talk about my favorite topic of the algorithms and the means plus function claims.
Mr. Johnson during his argument made a couple statements which I think illustrated exactly why their analysis is incorrect.

He said that in connection with the means plus function term, it is the operation that is patented.
And he said it is only the results that count.
And that is exactly what the United States Supreme Court said a means plus function claim cannot be interpreted to cover, or it is invalid back in 1946.
And that is why Congress stepped in and said, "No, we are going to insist that a means plus function claim be interpreted to incorporate the corresponding structure in the patent so it is not just the function."
It is not just the operation that is going to be covered.
It is going to be a specific way of implementing that function.
It is going to be a specific way of reaching that result that will be the subject of the patent.
So this I think illustrates the fundamental disagreement that we have about the proper way of interpreting an algorithm claim.
There is also an inconsistency in the way

they are trying to interpret the various algorithm claims in the different patents.
In our case, with every single claim means plus function term that includes a -- that corresponds to an algorithm, we have consistently said you need to take every single step in the algorithm discussed in the flow charts and the text of the patent that relates to that term.
In the plaintiffs' different claim constructions, they have taken various degrees of levels of specificity with respect to each term.
For example, in the '554 patent, when they are talking about a means detecting movement, they simply say, "Oh, this is just a patient motion detector."
Very clean and simple. Of course, that could cover just about anything.
But you contrast that with the way that their proposed interpretation of the terms in the '431 patent, if you look, for example, at the processing means in claim 26, they don't simply say oh, this is a image matching -- or image matcher which would be consistent with the way they adopted -- they have taken for the patient motion detector in the '554 patent.

Instead, presumably because they think it benefits them in some sort of infringement or invalidity manner, they have added a few arbitrary additional terms from the specific algorithmic components described in the specification.
And then they incorporated a different set of specifics, when they are talking about the tracking mechanism.
For example, there is an interesting question about why they think that the steps of coarse and fine alignment are things that should be considered part of the corresponding structure for one of the claims but not the other where they only talk about fiducials.
There is an inconsistency there, which is reflective of the fact they are simply going after something beneficial to them in this case and not doing a rigorous application of the appropriate legal principles that apply to this type of claim term.
In connection with a couple -- another sort of general theme that Mr. Johnson was enunciating is that Varian supposedly is trying to incorporate language from the specification in to

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the claim language that isn't reflected in any of the claim terms that are actually there.

That is not the case.

Let's take for example the portal image term.

If we go to a jury in this case and try to explain to them what a portal image is, to Dr. Balter he knows what a portal image is, but they will not know.

So we need to tell them what it is. That requires identifying certain characteristics of what a portal image is.

Those characteristics according to Dr. Balter including it is a megavolt image.

It captures the shape of the treatment beam, et cetera.

That is not importing new terms in to the claim.

It is simply explaining what the existing term is.

That is what a portal image is.

So it doesn't make sense to say I don't care if it is a portal image, that is a kilovolt image.

It is all a portal image.

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Well, it is not according to Dr. Balter.

Only certain types of images are portal images. Otherwise, a person of ordinary skill in the art would not understand it to be a portal image.

And that is the approach we have taken in a number of other terms.

We are trying to explain what existing terms in the claims are.

And in order to do that, sure, you have to use other language.

But that is not the same thing as simply plugging something in, because you want it to be there in the claim, when it is not there at all.

We are interpreting the words that are already in the claim.

There is one point that was made in connection with the Odetics case.

Mr. Johnson referred to several district court cases that have interpreted the Odetics case.

And there are a couple of district court cases from different districts in the country that seem to have interpreted Odetics in the way that Mr. Johnson has.

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But if you look at those cases, you are going to see there is no actual analysis of what Odetics said.

They interpreted it in a particular way without explaining why they were doing so.

They certainly didn't explain the analysis that I presented in great detail during my argument earlier.

And I think if you look at Odetics and truly analyze that case, you will see that it means what we said it does.

It only applies to infringement and not claim construction analysis.

And it doesn't change the conclusion the corresponding structure still has to include all of the structure disclosed in the specification.

There was discussion of the term successive, as it is useed in one of the claims of the '431 patent.

And Mr. Johnson said, "Well, you just take the ordinary meaning. It is nonambiguous."

But one of the primary principles of claim construction is that you don't interpret a word in a vacuum.

You have to interpret it in the context of

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the claim in which it appears.

The term "successive" appears in a claim that is talking about tracking.

And as Dr. Battler explained, tracking had an understood meaning in the art at the time of the patent, which means you are tracking motion in real-time.

You are not taking a point of position on one day and a point of position on another day and comparing them.

You are actually seeing what ongoing motion is, so you control the equipment.

And it is that context in which you have to consider the word "successive".

And it, therefore, doesn't mean just any two images taken at different points in time.

They are taken in a short period of time.

So the tracking function that is the subject matter of claim 21 of the '431 patent can actually occur.

And one other point I want to mention is the "of" versus "or" argument in connection with -- you are familiar with what I am talking about.

Here it is not just a matter of

interpreting the claim.

But there is an estoppel occurred because of the argument that the patentee made to the Patent and Trademark Office in order to overcome a specific piece of prior art.

So this isn't just a case where you are looking at the patent claim to see what it means.

They are estopped as a matter of law from arguing that it is broader than what they argued to the claim construction -- or to the patent office.

So there is a different principle involved here that the plaintiff has ignored.

And as a final point, I want to address the argument that the tracking and perhaps the matching process in the '431 patent can include the coarse alignment step without a fine alignment step following it.

Mr. Johnson suggested that oh, well, the patent says that after coarse alignment occurs and the matching process, then it gives the user an option of either accepting the coarse alignment or then going forward with the fine alignment.

Their claim construction based on that

discussion has suggested you might have an infringing apparatus that doesn't have any fine alignment option whatsoever.

That is not what the patent says.

The patented algorithm always at least gives the user the option of going forward with fine alignment.

The algorithm that is present always has a fine alignment capability in it.

It is just that in some circumstances, it may give the user an option with going forward.

Another it may just do it automatically.

There is no suggestion in the patent that you could cover an algorithm that only has coarse alignment with no fine alignment option or functionality following it.

Thank you very much for your time, your Honor.

JUDGE ZIEGLER: Thank you, counselors.

We will take this matter under advisement.

I would like to say your briefs were well prepared.

And this argument was ably presented.

I think the clients have been very capably represented in this case.

Have a safe trip home.

(Thereupon, at 3:30 o'clock p.m. the hearing was concluded.)

REPORTER'S CERTIFICATE

I, Lance E. Hannaford, certify that the foregoing two hundred eighty-three (283) pages are a true and correct transcript of my stenographic notes taken at the proceedings on Thursday, November 29, 2007, at the offices of 32nd Floor, One Oxford Centre, Pittsburgh, Pennsylvania 15219.

Lance E. Hannaford
Reporter

EXHIBIT D

08/739622

PATENT APPLICATION TRANSMITTAL LETTER
Case Docket No. #127442

THE COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C.

Sir:

Transmitted herewith for filing is the patent application of
Investors: ANDRE M. KALEND, JOEL GREENBERGER, KARUN B. SHIMOGA, CHARALAMBOS N. ATHANASSIOU and TAKEO KANADE
For: APPARATUS FOR MATCHING X-RAY IMAGES WITH REFERENCE IMAGES

Enclosed are:

- ■ EIGHT (8) sheets of (formal/informal) drawings,
- ■ An Assignment of the invention to THE UNIVERSITY OF PITTSBURGH,
- □ A certified copy of ______________________,
- □ An associate Power of Attorney, and
- ■ A verified statement to establish small entity status under 37 CFR §§ 1.9 and 1.27.

The filing fee has been calculated as shown below:

	(Col. 1)	(Col. 2)	SMALL ENTITY		OTHER THAN A SMALL ENTITY
FOR:	NO. FILED	NO. EXTRA	RATE FEE	OR	RATE FEE
BASIC FEE:			$385	OR	$770
TOTAL CLAIMS:	28-20=	* 8	x11= $ 88	OR	x22= $
INDEP. CLAIMS:	3-3=	*	x40= $	OR	x80= $
□ Multiple Dependent Claim			+130=$	OR	+260=$
			TOTAL $473.00		TOTAL $

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- □ Please charge my Deposit Account No. _______ in the amount of $_______. A duplicate copy of this sheet is enclosed.
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  - □ The issue fee set in 37 CFR § 1.18 at or before mailing of the Notice of Allowance, pursuant to 37 CFR § 1.311(b).
  - □ Any filing fees under 37 CFR § 1.16 for presentation of extra claims.

Date: October 29, 1996

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08/739022

APPARATUS FOR MATCHING X-RAY IMAGES WITH REFERENCE IMAGES

BACKGROUND OF THE INVENTION

Field of the Invention

This invention relates to matching similar x-ray images and has particular application to computer controlled radiotherapy apparatus for automatically matching on-line the portal images generated during radiotherapy treatment on a treatment machine with simulation images generated prior to treatment on a simulation machine for determining that the desired target is actually being irradiated for the purposes of assessment, and/or controlling the treatment equipment.

Background Information

There are medical applications which require matching of x-ray images. For instance, in computer controlled radiotherapy, treatment beams of high energy radiation are directed at a tumor from a number of directions so as to maximize irradiation of the tumor while minimizing exposure of healthy tissue surrounding the tumor. Such radiotherapy treatment typically has two distinct phases: the simulation phase, and the actual treatment phase. In the simulation phase, the patient is placed on equipment similar to the treatment equipment except that it does not generate the high energy radiation beam. The simulation equipment is successively positioned to simulate the delivery of the sequence of treatment beams prescribed by the treating oncologist. This assures that the equipment can be positioned to deliver the required treatment beams and progressively move from one treatment beam to the next without collision between the equipment and the patient or between movable components of the equipment. During this procedure a low dosage x-ray image called the simulation

image is taken. This simulation image, which generally has good contrast and detail because of the low energy of the x-ray beam used (in the kiloelectronvolt range) helps the oncologist to locate the position of the tumor and thereby establish the positions of the equipment components for delivering the successive treatment beams.

During the actual treatment phase, the patient is placed in the exact same position on the equipment as in the simulation before the regular-dosage x-ray radiation, typically in the megaelectronvolt range, is used to treat the patient. During this phase, another x-ray image is taken, which is called the portal image.

After completion of the treatment, the simulation and portal images are compared by an expert to determine whether the tumor, as identified in the simulation image, has been adequately treated with radiation in the portal image. If the coverage is not complete, the patient is scheduled for a corrective treatment.

The current accepted procedure involves the manual comparison of the portal and simulation images. Accurate manual comparison is quite challenging given the fact that the two x-rays are usually taken by different equipment and at different levels of radiation exposure. The latter fact implies that the tumor area is usually not visible in the portal x-ray, and thus the matching of the portal image with that of the simulation has to rely on manual estimation of dimensions from anatomical landmarks, which will not be clearly visible.

Conventionally, the portal images have been generated by using x-ray film which has to be developed. This is not a serious drawback where only a single or a few treatment beams are utilized. However, this x-ray film is a serious limitation in computer controlled radiotherapy where a large number of treatment beams are used. Electronic portal imagers have been developed which generate a digitized image which can be displayed on an electronic display device. Unfortunately, the same problems exist as to the contrast and definition in the portal image generated electronically.

The problem of matching portal images with simulation images is compounded by the fact that the images have differences in orientation caused by skewing, scaling differences, rotation, translation and differences in perspective and curvature.

In stereotactic radiology, digitized computed tomography x-ray images and magnetic resonance images (MRI) have been automatically matched by applying scaling derived from known fixed dimensions of a steel frame which appears in both

images. Such fixed landmarks of known dimensions are not available in conventional radiotherapy images.

There is a need, therefore, for apparatus for automatically matching x-ray images and particularly for matching portal images with simulation images in radiotherapy.

There is also a need for such apparatus which can match the portal and simulation images on-line for multiple treatment beams.

There is further need for such apparatus which can match portal images and simulation images having widely different contrast and definition and differences caused by skewing, rotation, scaling, perspective or curvature.

There is an additional need for apparatus for obtaining and maintaining alignment of a patient during computed controlled radiotherapy or for terminating the radiation beam if alignment becomes unacceptable.

SUMMARY OF THE INVENTION

These needs and others are satisfied by the invention which is directed to apparatus for automatically matching an x-ray image with a reference image, and particularly for matching the portal image with a simulation image for determining whether radiotherapy treatment has been adequate or for matching successive portal images for controlling operation of the radiotherapy equipment. In matching images, digitizing means digitizes the x-ray image such as the portal image to generate a first set of digital image signals or digital portal image signals (DPIS) in the case of the portal image. The digitizing means also digitizes the reference image such as the simulation image to generate second digital image signals or digital simulation signals (DSIS). Processing means process these digital image signals to generate matched digital image signals. The processing is performed without any prior knowledge of the physical dimensions of any of the features in the images. Output means generate for instance a display from the matched digital image signals and/or control the treatment/diagnosis equipment.

The processing means includes coarse alignment means which first effect a coarse alignment between the digital portal image signals and the digital simulation image signals. Coarse alignment is initiated by selecting seed points in the portal image represented by the DPIS and in the simulation image represented by the DSIS. Selection of the seed points can be done either interactively using a pointing device

such as a mouse to select what appear to be corresponding points on displays of the two images, or automatically through use of x-ray opaque fiducials placed on the patient. In either case, the seed points are used to compute a transform between the two images. Means are then used to apply the transform to one of the sets of digital image signals to transform points in that image to the coordinates of the other image thereby producing coarse aligned DPIS and DSIS.

Following coarse alignment, a fine alignment is performed. In implementing the fine alignment, the coarse aligned DPIS and DSIS are first prepared by selecting selected DPIS and selected DSIS for regions of the images which intersect or overlap, and preferably for a region of regular shape such as a rectangle within the intersecting regions of the images. The digital image signals for these regions are then enhanced to produce prepared images with similar dynamic range and pixel intensities. The fine alignment means includes means generating an updated transform from the prepared DPIS and DSIS, and means applying the updated transform to either the coarse or prepared DPIS and DSIS to generate the matched DPIS and DSIS.

The means generating the updated transform comprises means generating motion flow components from the prepared DPIS and DSIS and calculating means calculating the updated transform from the motion flow components. Preferably the means generating the motion flow components generates motion flow gradient components and the calculating means comprises means applying a robust optimization to calculate the updated transform. The means generating updated transform uses successive ascending levels of resolution of the prepared DPIS and DSIS to generate the updated transform.

In the tracking mode, the updated transform is used to track movement between successive sets of digital portal image signals. Tracking can be used to terminate the radiation if patient movement exceeds specified limits, or could be used to operate the patient positioning assembly to maintain the radiation beam in proper alignment with the area to be treated.

The invention can also be used to match x-ray images with other reference images which could be another x-ray image or another type of image.

BRIEF DESCRIPTION OF THE DRAWINGS

A full understanding of the invention can be gained from the following description of the preferred embodiments when read in conjunction with the accompanying drawings in which:

Figure 1 is a schematic diagram of apparatus for implementing the invention.

Figure 2a is a simplified illustration of a simulation image to which the invention can be applied.

Figure 2b is a simplified illustration of a portal image to which the invention may be applied.

Figure 2c is a simplified illustration of a display superimposing the simulation and portal images of Figures 2a and 2b utilizing the invention.

Figures 3-11 are flow charts of software utilized to implement the invention in the apparatus of Figure 1.

DESCRIPTION OF THE PREFERRED EMBODIMENT

The invention is directed to matching x-ray images with reference images and will be described as applied to matching portal images generated in computer controlled radiotherapy with simulation images. However, it will be understood that the invention has wide application in matching other x-ray images such as those used in diagnosis, for example. As will be seen, the invention also has application for tracking motion in successive portal images such as for controlling positioning of a patient or gating of the radiation beam.

Referring to Figure 1, a simulation setup 1 is used for determining the location of the region such as a tumor within a patient 3 to be treated and for setting up the sequence of treatment beams. The setup equipment includes a gantry 5 mounted for rotation about a horizontal pivot 7 supported by a machine base 9. A low energy, in the kiloelectronvolt range, x-ray beam 11 is directed by a collimator 13 mounted on the gantry 5 along a path which extends transversely through an extension of the pivot 7.

The patient 3 is supported on a patient positioning assembly 15 which includes a couch 17 mounted on a support 19 for three dimensional translation relative to the support. The support 19, in turn, is mounted on a turntable 21. Through

translation of the couch 17, rotation of the turntable 21 and rotation of the gantry 5 about the pivot 7, a plurality of treatment beams can be simulated. By sequencing the simulation equipment 1 through the positions required to generate the successive beams, it can be determined whether all of the required beams can be achieved and whether sequencing the movement of the equipment between beams must be adjusted to avoid collisions between the equipment and the patient or between components of the equipment.

The low energy x-ray beam 11 is used to generate simulation images by placement of an x-ray film 23 in line with the x-ray beam 11 on the other side of the patient 3 from the collimator 13. This simulation image is used to position the area of the patient to be treated, such as a tumor, at the isocenter of the setup, which is the intersection of the beam 11 with a projection of the pivot axis 7.

Following completion of the simulation, the patient 3 is transferred to the treatment setup 1'. As shown, the treatment setup at 1' is similar to the simulation setup 1, except that the x-ray beam 11' is in the megaelectronvolt range. A portal image is generated by the treatment setup 1'. This portal image can be captured by an x-ray film as in the simulation setup; however, it is preferred that an electronic portal imager 25 be used. If available, an electronic imager could also be used in place of the x-ray film 23 in the simulation setup 1.

As discussed above, the simulation image and the portal image can be quite different. One of the main reasons for this is the difference in the energy of the beams 11 and 11'. The invention can be used to match the simulation and portal images to determine if the treatment dosage was delivered to the proper treatment area. It can also be used to detect patient movement during treatment to terminate generation of the x-ray beam 11' if a movement exceeds proper limits, or to maneuver the equipment to maintain proper alignment.

The image matching system 27 includes a digitizer 29 which digitizes the simulation image such as produced on the x-ray film 23 and the portal image such as that generated by the electronic portal imager 25. In a more general sense, the matching system 27 matches an x-ray image, such as the portal image, with a reference image such as the simulation image.

The image matching system 27 further includes a processor 31 which includes a module for coarse alignment 33 followed by a module for fine alignment 35.

The output of the processor can be matched portal (x-ray) and simulation (reference) images which are displayed on a display device 37. Associated with the display device 37 are interface devices 39 which can include a keyboard 41 and a pointing device 43, such as a mouse or a trackball.

Figures 2a-2c illustrate that the invention can be used to match a portal x-ray image with a simulation reference image. Figure 2a represents a simulation image 45 generated using the simulation setup 1. The low energy x-rays used for this image produce an image with good contrast and detail, so that the outline 47 of the patient and bony structure 49 are shown as well as the tumor 51. Figure 2b illustrates the portal image which being taken with the higher energy treatment beam shows the treated area 55 as a uniform dark spot. The irregular edge of the treated area 55 is produced by the leaves used in the collimator 13 to conform the beam 11′ generally to the shape of the tumor. The remainder of the portal image 55 shows little detail and does not indicate the location of the bones. As can be seen, the two images 45 and 53 can be translated relative to each other, scaled differently, skewed and rotated (by 90° in the example). The two images can also be different in perspective and in curvature.

The coarse alignment module 33 produces a general alignment of the two images, and then the fine alignment module 35 uses robust motion flow to rapidly and accurately complete matching of the images. The display device 37 can present the matched images in different ways. In one embodiment, the display 37 alternates between the two images at about 6 to 20 Hz, but usually about 12 Hz, so that the observer views the images superimposed as a composite image 59, as shown in Figure 2c. As can be seen in the example, the treated area 55′ in the matched portal image, overlays the tumor 51′ in the matched simulation image. In another type of display (not shown), the outline of the treated area from the portal image is projected onto the processed simulation image, so that it can be seen if the targeted tumor was in fact treated.

In performing the coarse alignment, a coarse transformation is applied to the digitized x-ray or portal image signals (DPIS) to convert them to the coordinate system of the digital reference or simulation image signals (DSIS). As will be seen, the information needed to generate this transformation can be generated interactively through selection of what appear to be corresponding points in the two images by the operator interactively using a pointer device 43 or automatically using x-ray opaque

fiducials 61 which are placed on the patient in both the simulation setup and the treatment setup (see Figure 1). The points so generated in either case are referred to as seed points. The coarse transform H from the portal image coordinates to the simulation coordinates is:

$$\begin{bmatrix} simulation_x \\ simulation_y \\ 1 \end{bmatrix} = \begin{bmatrix} RotSkewScale_a & RotSkewScale_b & translation_x \\ RotSkewScale_c & RotSkewScale_d & translation_y \\ 0 & 0 & 1 \end{bmatrix} \cdot \begin{bmatrix} portal_x \\ portal_y \\ 1 \end{bmatrix} \quad \text{(EQ. 1)}$$

The (x y) vector denotes the column and row coordinates of the center of each of the seed points in the corresponding portal and simulation images. The four *RotSkewScale* components of the matrix describe the full affine transformation that is needed to coarsely align the images. In this stage, the placement of the fiducial or the interactive selection of the seed points need not be accurate as the next stage is able to accommodate for reasonably small deviations.

Using the results of the coarse alignment, the portal image is warped toward the simulation image. Then, overlapping regions of the two images are computer enhanced so that the corresponding intensity levels are similar. Finally, the motion-flow, or the fine-scale transform is computed so that the portal image glides on the gradient of dissimilarity toward the simulation image. In this stage, a more comprehensive transformation model is used in which the input position vector is represented by:

$$X(x) = \begin{bmatrix} 1 & x & y & 0 & 0 & 0 & x^2 & x \cdot y & 0 \\ 0 & 0 & 0 & 1 & x & y & x \cdot y & y^2 & x^2 \end{bmatrix} \quad \text{(EQ.2)}$$

and the transformation matrix is represented by:

$$Q = \begin{bmatrix} \alpha_0 & \alpha_1 & \alpha_2 & \alpha_3 & \alpha_4 \alpha_5 & p_0 & p_1 & c \end{bmatrix}^T \quad \text{(EQ. 3)}$$

so that the result is:

$$u\,(x;Q)=X\,(x)\cdot Q \qquad \text{(EQ. 4)}$$

whereΔ portal $(x;Q)$ = $u(x;Q)$ and portal (x) = $X\,(x)$. The parameters α_o through α_5 include the affine transform as in the coarse alignment, whereas the parameters p_o, p_1 include the perspective transformation, and c covers the deformation that can be caused by breathing, etc.

To recover the parameters of the vector Q we formulate the image dissimilarity as a result of motion-flow, or distance between the two images.

$$I(x,t) = I(x - (X(x) \cdot Q_{f,t+1})) \qquad \text{(EQ. 5)}$$

for $\forall x \in f$, where f is the region of the image we compute the transformation over. In (EQ. 5), $I(x)$ is the intensity function at point x, the image at $t + 1$ is the portal image, and at t is the simulation image. By using various derivation techniques, we formulate the motion-flow using the gradient (or dissimilarity gradient) as below:

$$\nabla I(X(x) \cdot Q_f) + \frac{\partial I}{\partial t} = 0 \qquad \text{(EQ. 6)}$$

for $\forall x \in f$.

In this stage, a robust regression method is employed, using unconstrained optimization, to calculate the elements of Q (see (EQ. 3)). This technique enables us to cope with the 'reasonably small' deviations from the coarse alignment stage, as well as any residual dissimilarity between the two images. Using the robust technique ensures that only the dominant transformation will be recovered without running into the risk of being affected by the noise and residual errors.

Figures 3-11 are flow charts of software which implements the invention. Figure 3 illustrates the main routine 100 which includes performing a coarse alignment, either interactively at block 110 or automatically at block 120. In both cases a rough approximation of the transformation between the portal image and

the simulation image is calculated using Equation 1. The user then has the option of determining whether the rough approximation has provided a satisfactory alignment of the images at 130. If so, the procedure is completed. If not, a fine alignment is performed. As discussed, the invention can also be used to track patient movement, in which case the transformation between the two images is utilized at 140 to roughly determine the updated position of the fiducials. If requested by the user in image matching and during tracking, the images are prepared for the fine alignment at 150. The refined image transformation is then calculated at 160 and if the image matching mode is selected as determined at 170, the transform is accomplished and the images are displayed at 180 in the manner discussed above. If the tracking mode has been selected at 190, the routine returns to 140 for generating the next position. The user again has the final decision at 200 to determine whether the image matching is satisfactory. If not, the routine returns to 110 and the rough calculation is re-initiated.

The procedure for calculating the rough approximation of the transformation interactively called for at block 110 in Figure 3 is illustrated in detail in Figure 4. The user selects corresponding seed points or areas in the portal image and the simulation image using, for instance, the mouse 43 as indicated at 111. The selected areas or points are then used to compute the rough transformation between the portal image and the simulation image by calling a procedure A as indicated at 112. This rough transform is then used to transform the portal image to simulation image coordinates by calling procedure B as indicated at 113. The images are then displayed on the monitor 37 as indicated at 114.

The details of procedure A used to calculate the rough transform are shown in Figure 5. If the user has indicated an area as determined at A1, the system automatically selects random points from inside the area as corresponding as indicated at A2. Then, or if the user has selected points rather than an area, the corresponding point pairs are used to calculate the transform parameters using the least squares (LSQ) method as indicated at A3.

The details of procedure B for transforming the portal to simulation coordinates is shown in Figure 5. First, the row and column limits of the resulting transformed portal image are determined at B1 using the transformation matrix H, which is the inverse of Equation 1. The resulting portal image is then raster scanned at B2, and for each pixel the location is determined using the transformation. The

intensity value for each pixel is calculated next using linear interpolation between the surrounding pixel locations in the original portal image.

The routine 124 for performing the coarse alignment automatically using fiducials on the patient is shown in Figure 7. The x-ray opaque fiducials 61 are detected in both the portal and simulation images at 121 and the corresponding markers are identified at 122. The image transform is then computed at 123 using procedure A of Figure 5 and the centroid of each of the markers as the seed points. The portal image is then transformed to simulation coordinates using the computed transformation and procedure B of Figure 6. When in the matching mode as determined at 125, the images are displayed at 126 in the manner discussed above in connection with Figures 2a-c.

The routine 150 for preparing the coarse aligned digital image signals for fine alignment is shown in Figure 8. First, the region of intersection over overlap between the simulation and portal images is calculated at 151 using the transformation of Equation 1. Next, the largest rectangular region that fits within the intersection region is calculated at 152. Other regular geometric shapes, such as a square and so forth, could be used in place of the rectangle. New images representing the rectangular intersection region of the portal and simulation image are formed at 153. These resulting images are then enhanced at 154 to generate prepared digital image signals. Various forms of enhancement such as histogram equalization, lapalcian of the Gaussian, high-pass filtering and other techniques are used to produce the prepared images with similar dynamic range and pixel intensities.

Figure 9 illustrates the routine 160 for calculating the updated transformation for a fine alignment. This process is performed at several levels of resolution of the digital image signals beginning with the lowest resolution, which in the example is about one-eighth resolution. Thus, at 161 the images at the lowest resolution for the prepared portal and simulation images are formed. These images are updated using the latest updated transformation parameters, that is, transformation parameters calculated at the previous level of resolution, at 162. An important part of the invention is that robust motion flow is used to perform the fine alignment. In particular, the motion flow gradient components are generated at 163. Application of motion flow using gradient components is described by M. J. Black and P. Anandan in a paper entitled, "*A Framework For The Robust Estimation Of Optical Flow*"

published in Proc. 4th Intl. Conf. on Computer Vision (ICCV 93), Berlin, Germany, May 1993. Motion flow is applied to the motion required to cause pixels on one image to flow into alignment with corresponding pixels in the other image. Robust motion applies to the motion by which most of the pixels which have moved have moved similarly, while there may be others exhibiting different motion. The updated image transformation parameters are then calculated at 164 using robust optimization. If the upper limit of resolution has not heen reached as determined at 165, then the resolution is incremented at 166 and updated transformation parameters are recalculated at the new level of resolution.

When the highest level of resolution has been reached at 165, the final transformation matrix Q is generated at 167. The details of the routine for calculating the updated image transformation parameters using robust optimization of block 164 in Figure 9 is shown in Figure 10. As described in the paper by Black and Anandan discussed above, the robust motion is represented by data points called inliers. Those exhibiting other motion are identified as outliers. In the present invention, the data points are the pixel values. The pixels are successively separated into inliers and outliers based upon their contribution to a consistent motion flow vector. The pixels in the inlier set are used to calculate the dominant motion flow, and their contribution to it is dependent on their weight factors which are calculated during the robust optimization.

Referring particularly to Figure 10, a loop is entered at 164.1 where each of the inlier points is marked using individual weight factors. Initially, the weight factors of the pixels are all set to 1 so that all of the pixels are inliers. At 164.2, an optimization parameter, σ, which determines the sensitivity of the procedure to outliers is set. The weight factors are dependent on this parameter, σ. The lower the value of σ, the more points are eliminated as inliers and the closer the inliers become to the current estimate of the motion flow vector. Hence, a large σ is used initially so that all points are included. On successive loops, σ is lowered to eliminate more and more outliers. This lowering of σ is referred to as σ scheduling. The σ scheduling must be done carefully. If σ is lowered too fast, a solution may be missed, while on the other hand, lowering σ too slowly increases the processing time. In accordance with the invention, σ is lowered depending upon the largest error in the motion flow parameters. Following this, another loop is entered at 164.3 in which each of the inlier data points

is used in the calculation of the updated values for the transformation parameters of the Q matrix at 164.4. The equations used at 164.4 are derived preferably using the conjugate gradient, although gradient descent can also be used. In addition, motion flow and robust statistics are used in deriving equations for determining the transformation parameters. The error in the transformation parameters, which is the change from the last calculation, as well as σ, are used at 164.5 to adjust the weight factors for the pixels. When all of the inlier data points/pixels have been used as determined at 164.3, a check is made at 164.6 to determine if the solution has converged to the desired degree. If not, the routine returns to 164.1 and the inlier data points are again marked using the updated weight factors.

Figure 11 illustrates the tracking routine on 140. As indicated at 141, the incremental updates and the transform H and/or Q are combined so that the transform always relates back to the original simulation or reference image. On the initial pass through the tracking routine, the then current portal image replaces the simulation image if used, and then a new portal image is acquired at 143. As tracking continues, successive portal images are matched with the next preceding portal image to generate the updated transform. As indicated at 144, the successive positions of the fiducials or changes in the pattern of the fiducials from successive portal images is used to generate tracking signals for controlling the radiotherapy equipment such as turning the beam on and off and/or driving the patient positioning assembly.

While specific embodiments of the invention have been described in detail, it will be appreciated by those skilled in the art that various modifications and alternatives to those details could be developed in light of the overall teachings of the disclosure. Accordingly, the particular arrangements disclosed are meant to be illustrative only and not limiting as to the scope of invention which is to be given the full breadth of the claims appended and any and all equivalents thereof.

What is Claimed is:

1. Apparatus for automatically matching a portal image with a simulation image, said apparatus comprising:

means digitizing said portal image and simulation image to generate digital portal image signals (DPIS) and digital simulation image signals (DSIS), respectively;

processing means processing said DPIS and said DSIS to generate matched DPIS and DSIS; and

output means for generating an output from said matched DPIS and DSIS.

2. The apparatus of Claim 1, wherein said processing means comprises coarse alignment means generating coarse aligned DPIS and DSIS from said DPIS and DSIS, and fine alignment means generating said matched DPIS and DSIS from said coarse aligned DPIS and DSIS for overlapping regions of said simulation and portal images.

3. The apparatus of Claim 2, wherein said coarse alignment means comprises means selecting corresponding seed points in said portal image represented by said DPIS and said simulation image represented by said DSIS, means computing a transform between said portal image and said simulation image from said corresponding seed points, and means applying said transform to one of said DPIS said DSIS to generate with the other of said DPIS and DSIS said coarse aligned DPIS and DSIS.

4. The apparatus of Claim 3, wherein said means selecting corresponding seed points comprises interactive means selecting corresponding points in displays generated from said DPIS and DSIS.

5. The apparatus of Claim 3, wherein said means selecting corresponding seed points comprises means detecting x-ray opaque fiducials in said DPIS and said DSIS, and means identifying corresponding fiducials in said DPIS and DSIS as said corresponding seed points.

6. The apparatus of Claim 3, wherein said fine alignment means comprises means generating prepared DPIS and DSIS from said coarse aligned DPIS and DSIS, means generating an updated transform from said prepared DPIS and DSIS, and means applying said updated transform to one of said coarse and prepared DPIS and DSIS to generate said matched DPIS and DSIS.

7. The apparatus of Claim 2, wherein said fine alignment means comprises means generating prepared DPIS and DSIS from said coarse aligned DPIS and DSIS, means generating an updated transform from said prepared DPIS and DSIS, and means applying said updated transform to one of said coarse and prepared DPIS and DSIS to generate said matched DPIS and DSIS.

8. The apparatus of Claim 7, wherein said means generating said prepared DPIS and DSIS comprises means selecting selected DPIS and selected DSIS for regions of images represented by said DPIS and DSIS which intersect.

9. The apparatus of Claim 8, wherein said means generating said prepared DPIS and DSIS further includes means enhancing said selected DPIS and DSIS.

10. The apparatus of Claim 9, wherein said means selecting said selected DPIS and selected DSIS further includes means selecting DPIS and DSIS within a portion of regions of images represented by said DPIS and DSIS, which have a predetermined regular shape.

11. The apparatus of Claim 7, wherein said means generating said updated transform comprises means generating motion flow components from said prepared DPIS and DSIS and calculating means calculating said updated transform from said motion flow components.

12. The apparatus of Claim 11, wherein said means generating motion flow components generates motion flow gradient components, and said calculating means comprises means applying a robust optimization to calculate said updated transform.

13. The apparatus of Claim 12, wherein said means generating said updated transform comprises utilizing said means generating motion flow gradient components and said calculating means repetitively using successive ascending levels of resolution of said prepared DPIS and DSIS.

14. The apparatus of Claim 7, wherein said means generating said updated transform comprises means using successive ascending levels of resolution of said prepared DPIS and DSIS to generate said updated transform.

15. The apparatus of Claim 7, wherein said means generating said updated transform comprises means applying robust motion flow to said prepared DPIS and DSIS.

16. The apparatus of Claim 15, wherein said means applying robust motion flow to said prepared DPIS and DSIS applies robust motion flow to successive ascending levels of resolution of said DPIS and DSIS.

17. The apparatus of Claim 1, wherein said output means comprises display means generating a display from said matched DPIS and DSIS.

18. The apparatus of Claim 1, wherein said output means comprises tracking means tracking movement in said image represented by said DPIS.

19. The apparatus of Claim 18, wherein said output means further includes positioning means positioning a patient relative to a radiation beam which generates said portal image, and means controlling said positioning means in response to movement tracked by said tracking means.

20. The apparatus of Claim 18 wherein said output means includes means controlling generation of a radiation beam producing said portal image in response to movement tracked by said tracking means.

21. Apparatus for matching portal images to control radiotherapy/diagnosis equipment, said apparatus comprising:

means digitizing successive portal images to generate successive sets of digital portal image signals (DPIS); and

tracking means tracking movement between successive sets of DPIS.

22. The apparatus of Claim 21, wherein said tracking means comprises means generating an updated transform between successive portal images by

applying robust motion flow to said successive sets of DPIS and means using said updated transform to track said movement between said successive sets of DPIS.

23. The apparatus of Claim 22, wherein said means generating said updated transform comprises means generating motion flow components from said successive sets of DPIS, and means calculating said updated transform between successive portal images using said motion flow components.

24. The apparatus of Claim 23, wherein said means generating motion flow components generates motion flow gradient components, and wherein said calculating means comprises means applying a robust optimization to calculate said updated transform.

25. The apparatus of Claim 24, wherein said means generating said updated transform comprises means utilizing said means generating motion flow gradient components and said calculating means repetitively using successive ascending levels of resolution of said successive sets of DPIS.

26. Apparatus for automatically matching an x-ray image with a reference image, said apparatus comprising:

means digitizing said x-ray image and reference image to generate first digital image signals and second digital image signals, respectively;

processing means processing said first and second digital signals without input of any physical dimensions of any features within said images to generate matched digital image signals; and

display means generating a display from said matched digital image signals.

27. The apparatus of Claim 26 wherein said processing means comprises coarse alignment means generating coarse aligned digital images signals from said first and second digital image signals, and fine alignment means generating a transform between said coarse aligned digital image signals for overlapping regions of said x-ray and reference images utilizing robust motion flow, and means applying said transform to one of said coarse aligned digital image signals to generate said matched digital image signals.

28. The apparatus of Claim 27 wherein said fine alignment means comprises means enhancing said coarse aligned digital image signals to generate prepared coarse aligned image signals having similar dynamic ranges and intensities,

and means generating said transform between said prepared coarse aligned digital image signals utilizing robust motion flow.

08/739622

ABSTRACT OF THE DISCLOSURE

X-ray images such as radiotherapy portal images and simulation images are matched by apparatus which digitizes the images and automatically processes the digitized signals to generate matched digitized signals which can be displayed for comparison. The digitized images are first coarse aligned using a transform generated from seed points selected interactively from the two images or through detection and identification of x-ray opaque fiducials placed on the patient. A fine alignment is then performed by first selecting intersecting regions of the two images and enhancing those regions. Secondly, an updated transform is generated using robust motion flow in these regions at successive ascending levels of resolution. The updated transform is then used to align the images which are displayed for comparison. The updated transform can also be used to control the radiotherapy equipment.

01/16/97 13:43 ☎ 002/004

DECLARATION FOR PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled __APPARATUS FOR MATCHING X-RAY IMAGES WITH REFERENCE IMAGES__ the specification of which (check one)

_X_ is attached hereto.
___ was filed on ______________ as Application Serial No. __________ and was amended on ______________.
(if applicable)

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, §1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application[s] for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

PRIOR FOREIGN APPLICATION(S)

			Priority claimed	
NONE				
(Number)	(Country)	(Day/month/year filed)	Yes	No
(Number)	(Country)	(Day/month/year filed)	Yes	No
(Number)	(Country)	(Day/month/year filed)	Yes	No

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application[s] listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose to the United States Patent and

Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, §1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application:

NONE
(Application Serial No.) (Filing Date) (Status--patented, pending, abandoned)

(Application Serial No.) (Filing Date) (Status--patented, pending, abandoned)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

I hereby appoint Walter J. Blenko, Jr., Registration No. 18,526; Arnold B. Silverman, Registration No. 22,614; Richard V. Westerhoff, Registration No. 24,454; Lewis F. Gould, Jr., Registration No. 25,057; Stephan P. Gribok, Registration No. 29,643; Frederick A. Tecce, Registration No. 32,065; Alan G. Towner, Registration No. 32,949; David V. Radack, Registration No. 33,442; Kirk D. Houser, Registration No. 37,357; Richard P. Gilly, Registration No. 37,630; Diane R. Meyers, Registration No. 38,968; and Daniel S. Goldberg, Registration No. 39,689, as my attorneys or agents with full power of substitution and revocation, to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith, to amend the specification, to appeal in case of rejection, as they may deem advisable, to receive the patent when granted and generally to do all matters and things needful in the premises as fully and to all intents and purposes as I could do.

Please direct all correspondence to: Richard V. Westerhoff
Eckert Seamans Cherin & Mellott, 600 Grant Street, Forty-second Floor, Pittsburgh, Pennsylvania 15219, (412) 566-6000.

Full name of sole or first joint inventor **Andre M. Kalend**
Inventor's signature ___ Date 10-20-98
Residence **Monroeville, PA**
Citizenship **Zaire**
Post Office Address **103 Trotwood Drive, Monroeville, PA 15146**

Full name of second joint inventor, if any **Joel Greenberger**
Inventor's signature ___ Date 10/21/98
Residence **Sewickley, PA**
Citizenship **United States of America**
Post Office Address **749 Chestnut Street, Sewickley, PA 15143**

3 (x)

Full name of third joint inventor, if any Karun B. Shimoga
Inventor's signature Date Oct 18, 96
Residence Pittsburgh, PA
Citizenship India
Post Office Address 5030 Centre Avenue, Apt. #560, Pittsburgh, PA 15213

(4 x)

Full name of fourth joint inventor, if any Charalambos N. Athanassiou
Inventor's signature Date 9/23/96
Residence Athens, Greece GRX
Citizenship Greece
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5 (x)

Full name of fifth joint inventor, if any Takeo Kanade
Inventor's signature Date Oct 18, 1996
Residence Pittsburgh, PA
Citizenship Japan
Post Office Address 130 Penrose Dr., Pittsburgh, PA 15208

Andre M. Kalend et al. Attorney's Docket No: 127442

ATCHING X-RAY IMAGES WITH REFERENCE IMAGES

ERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS
(37 CFR 1.9(f) and 1.27(d)) - NONPROFIT ORGANIZATION

hat I am an official empowered to act on behalf of the nonprofit organization

NIZATION University of Pittsburgh of the Commonwealth System of Higher Educati
ORGANIZATION 911 William Pitt Union
Pittsburgh, PA 15260

E OF ORGANIZATION

[X] UNIVERSITY OR OTHER INSTITUTION OF HIGHER EDUCATION
[ ] TAX EXEMPT UNDER INTERNAL REVENUE SERVICE CODE (26 USC 501(a) and 501(c)(3))
[ ] NONPROFIT SCIENTIFIC OR EDUCATIONAL UNDER STATUTE OF STATE OF THE UNITED STATES OF AMERICA
(NAME OF STATE ______)
(CITATION OF STATUTE ______)
[ ] WOULD QUALIFY AS TAX EXEMPT UNDER INTERNAL REVENUE SERVICE CODE (26 USC 501(a) and 501(c)(3)) IF LOCATED IN THE UNITED STATES OF AMERICA
[ ] WOULD QUALIFY AS NONPROFIT SCIENTIFIC OR EDUCATIONAL UNDER STATUTE OF STATE OF THE UNITED STATES OF AMERICA IF LOCATED IN THE UNITED STATES OF AMERICA
(NAME OF STATE ______)
(CITATION OF STATUTE ______)

I hereby declare that the nonprofit organization identified above qualifies as a nonprofit organization as defined in 37 CFR 1.9(e) for purposes of paying reduced fees under section 41(a) and (b) of Title 35, United States Code with regard to the invention entitled APPARATUS FOR MATCHING X-RAY IMAGES WITH REFERENCE IMAGES
by inventor(s) Andre M. Kalend, Joel Greenberger, Karun B. Shimoga, Charalambos N. Athanassiou and Takeo Kanade
described in
[x] the specification filed herewith
[ ] application Serial No. ______, filed ______
[ ] Patent No. ______, issued ______

I hereby declare that rights under contract or law have been conveyed to and remain with the nonprofit organization with regard to the above-identified invention.

If the rights held by the nonprofit organization are not exclusive, each individual, concern or organization having rights to the invention is listed below* and no rights to the invention are held by any person, other than the inventor, who could not qualify as a small business concern under 37 CFR 1.9(d) or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e). *NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

NAME University of Pittsburgh
ADDRESS 911 William Pitt Union, Pittsburgh, PA 15260
[ ] INDIVIDUAL [ ] SMALL BUSINESS CONCERN [x] NONPROFIT ORGANIZATION

NAME
ADDRESS
[ ] INDIVIDUAL [ ] SMALL BUSINESS CONCERN [ ] NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF PERSON SIGNING Frances J. Connell
TITLE IN ORGANIZATION Director, Office of Intellectual Property
ADDRESS OF PERSON SIGNING 911 William Pitt Union, Pittsburgh, PA 15260
X Frances J. Connell DATE October 29, 1996

01/16/97 13:43 ☎ 001/004

FACSIMILE

To: PAULENE TEMONEY

Company: U.S. PATENT & TRADEMARK OFFICE

Fax Number: 1-703-308-7750

Confirmation Number:

Date: 1/16/97 Time: 2:00 p.m.

From: **Richard V. Westerhoff, Esquire**

Direct Dial: (412) 566-6105

Message: RE: DOCKET NO. 127442

PER YOUR TELEPHONE REQUEST OF TODAY, ATTACHED IS A COPY OF THE DECLARATION AND POWER OF ATTORNEY MAILED TO YOUR OFFICE ON 10/29/96.

We are transmitting 4 pages, including this page.

600 Grant Street, 42nd Floor Pittsburgh, Pennsylvania 15219-2788
412/ 566-6000 Facsimile 412/ 566-6099

Pittsburgh Harrisburg Allentown Philadelphia Boston

ATION FOR PATENT APPLICATION

or, I hereby declare that:

sid address and citizenship are stated below next to my name.

I believe I am the o ginal, first and sole inventor (if only one name is listed below) or an ial, first and joint inventor (if plural names are listed below) of the subject matter which is claimed for which a patent is sought on the invention entitled **APPARATUS FOR MATCHING X-Y IMAGES WITH REFERENCE IMAGES** specification of which (check one)

X is attached hereto.

____ was filed on ____________ as Application Serial No. __________ and was amended on ____________.
(if applicable)

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, §1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application[s] for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

PRIOR FOREIGN APPLICATION(S)

			Priority claimed	
NONE				
(Number)	(Country)	(Day/month/year filed)	Yes	No
(Number)	(Country)	(Day/month/year filed)	Yes	No
(Number)	(Country)	(Day/month/year filed)	Yes	No

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application[s] listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose to the United States Patent and

Trademark Office all information wn to me to be material to patentabi as defined in Title 37, Code of Federal Regulations, §1.56 which became available between th filing date of the prior application and the national or PCT international filing date of this application:

NONE
(Application Serial No.) (Filing Date) (Status--patented, pending, abandoned)

(Application Serial No.) (Filing Date) (Status--patented, pending, abandoned)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

I hereby appoint Walter J. Blenko, Jr., Registration No. 18,526; Arnold B. Silverman, Registration No. 22,614; Richard V. Westerhoff, Registration No. 24,454; Lewis F. Gould, Jr., Registration No. 25,057; Stephan P. Gribok, Registration No. 29,643; Frederick A. Tecce, Registration No. 32,065; Alan G. Towner, Registration No. 32,949; David V. Radack, Registration No. 33,442; Kirk D. Houser, Registration No. 37,357; Richard P. Gilly, Registration No. 37,630; Diane R. Meyers, Registration No. 38,968; and Daniel S. Goldberg, Registration No. 39,689, as my attorneys or agents with full power of substitution and revocation, to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith, to amend the specification, to appeal in case of rejection, as they may deem advisable, to receive the patent when granted and generally to do all matters and things needful in the premises as fully and to all intents and purposes as I could do.

Please direct all correspondence to: Richard V. Westerhoff
Eckert Seamans Cherin & Mellott, 600 Grant Street, Forty-second Floor, Pittsburgh, Pennsylvania 15219, (412) 566-6000.

Full name of sole or first joint inventor Andre M. Kalend
Inventor's signature A. M. Kalend Date 10-20-96
Residence Monroeville, PA
Citizenship Zaire
Post Office Address 103 Trotwood Drive, Monroeville, PA 15146

Full name of second joint inventor, if any Joel Greenberger
Inventor's signature Joel G Date 10/21/96
Residence Sewickley, PA
Citizenship United States of America
Post Office Address 749 Chestnut Street, Sewickley, PA 15143

Full name of third joint inventor, if any Karun B. Shimoga
Inventor's signature Karun B. Shimoga Date Oct 18, 96
Residence Pittsburgh, PA
Citizenship India
Post Office Address 5030 Centre Avenue, Apt. #560, Pittsburgh, PA 15213

Full name of fourth joint inventor, if any Charalambos N. Athanassiou
Inventor's signature [signature] Date 9/23/96
Residence Athens, Greece

Citizenship Greece
Post Office Address c/o I. Athanassiou, Derigny 8, Athens 10434 GREECE

Full name of fifth joint inventor, if any Takeo Kanade
Inventor's signature T Kanade Date Oct 18, 1996
Residence Pittsburgh, PA
Citizenship Japan
Post Office Address 130 Penrose Dr., Pittsburgh, PA 15208

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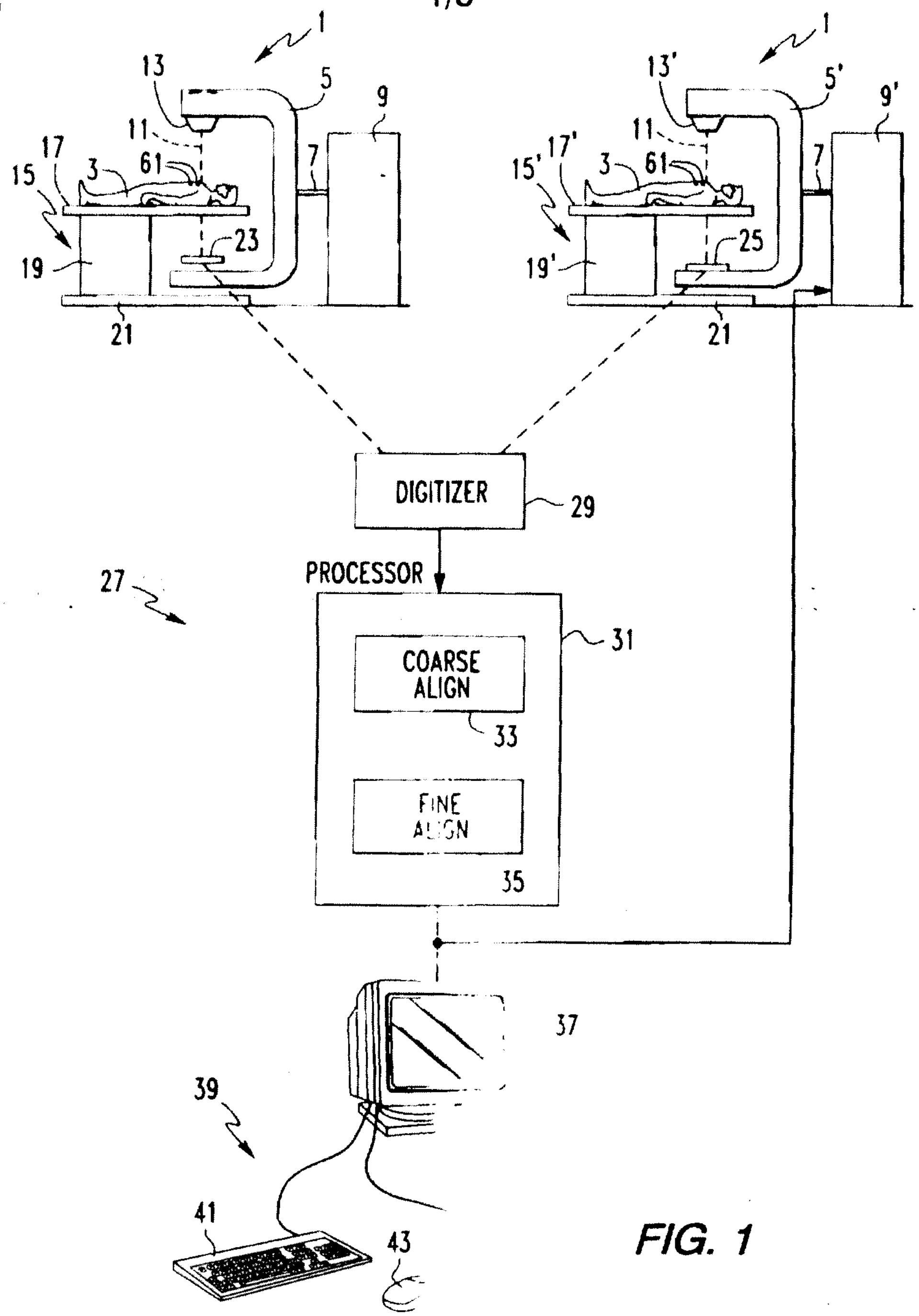

FIG. 1

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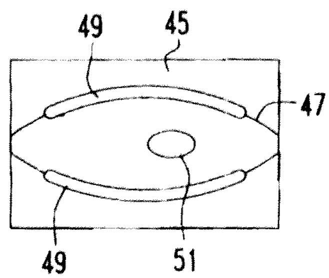

FIG. 2a

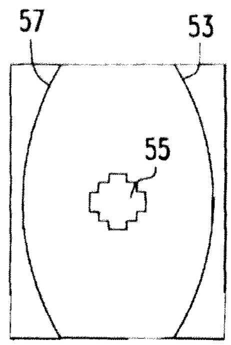

FIG. 2b

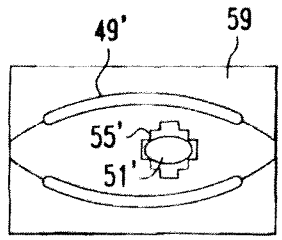

FIG. 2c

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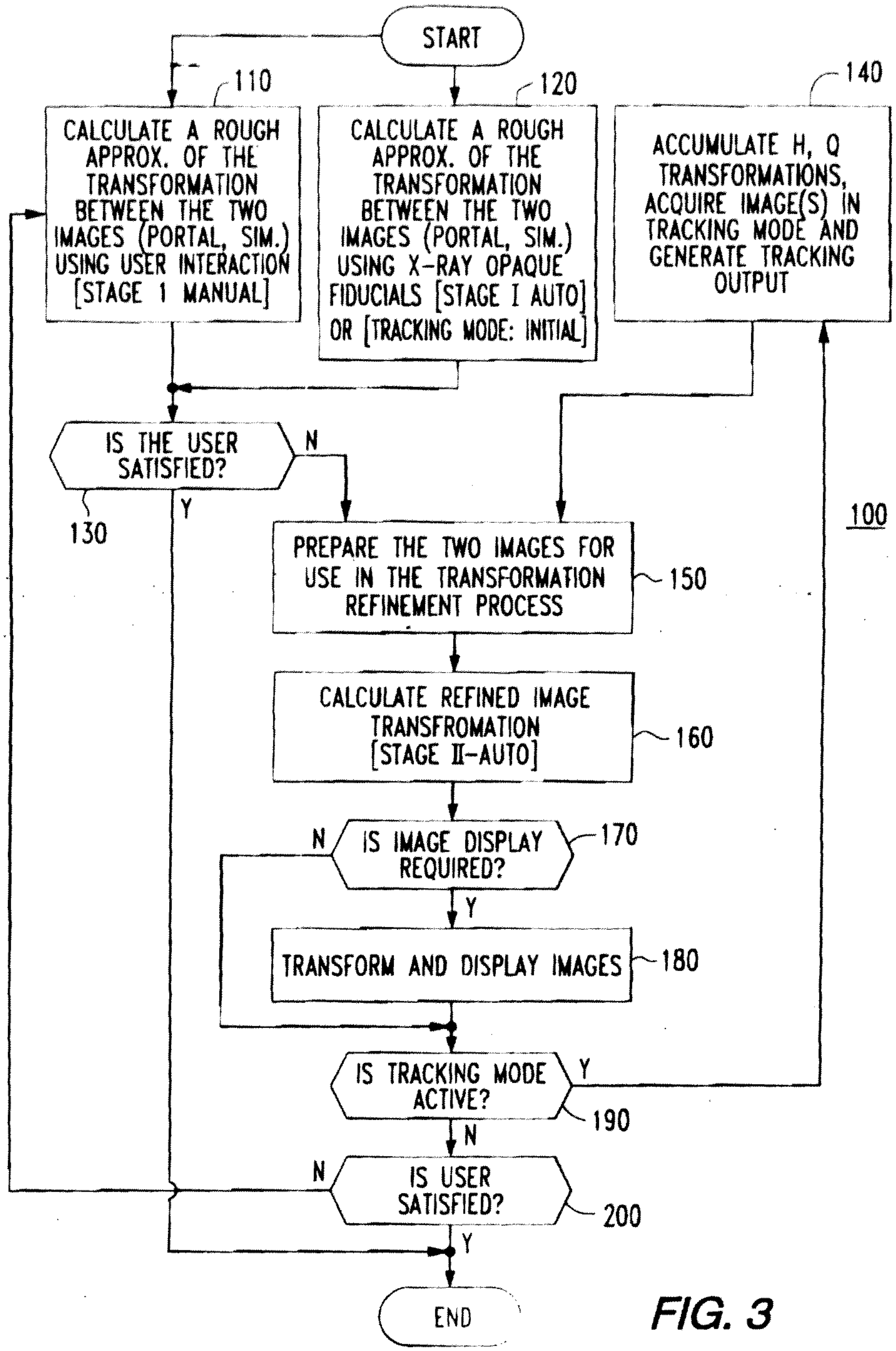

FIG. 3

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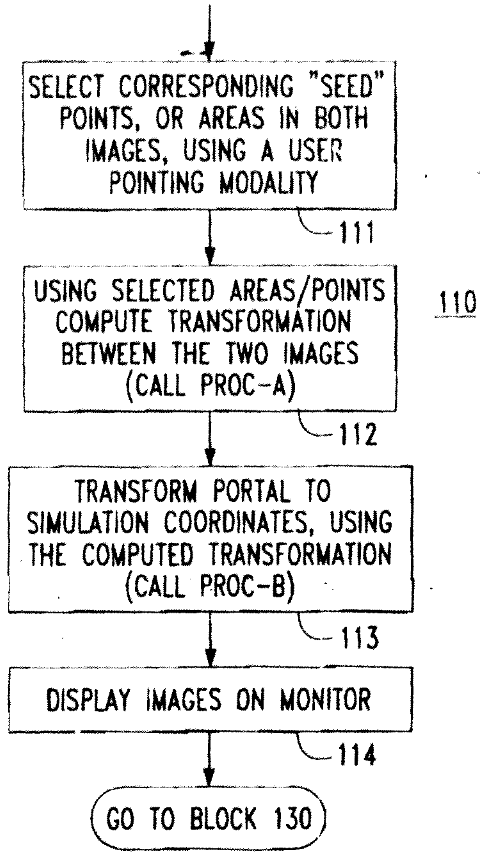

FIG. 4

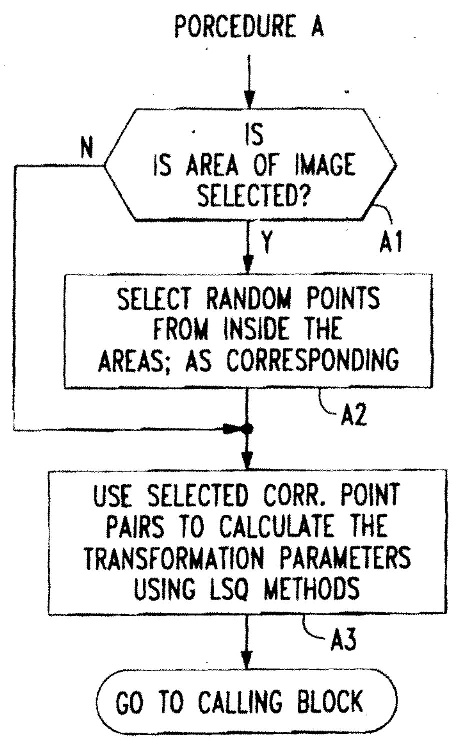

FIG. 5

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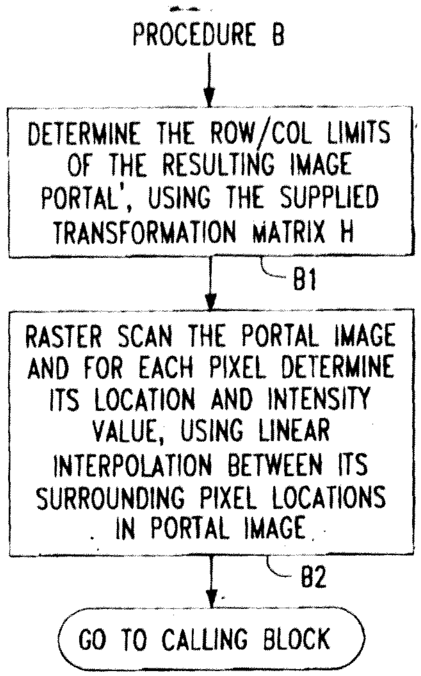

FIG. 6

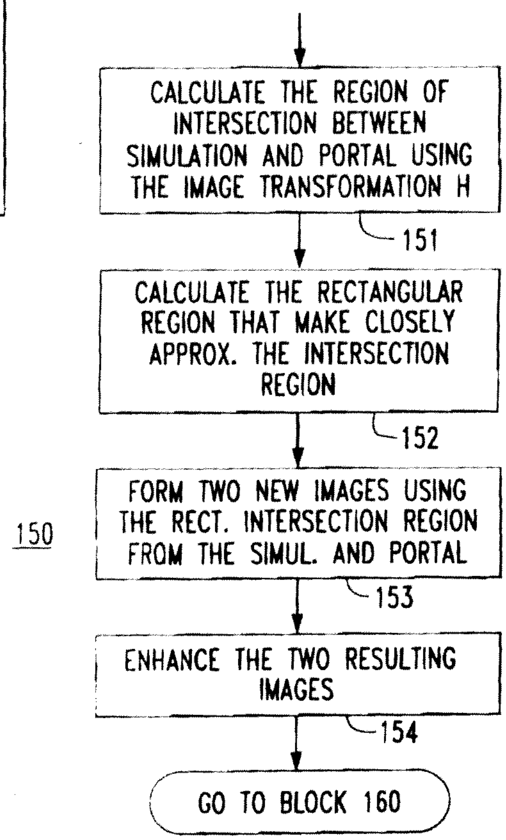

FIG. 8

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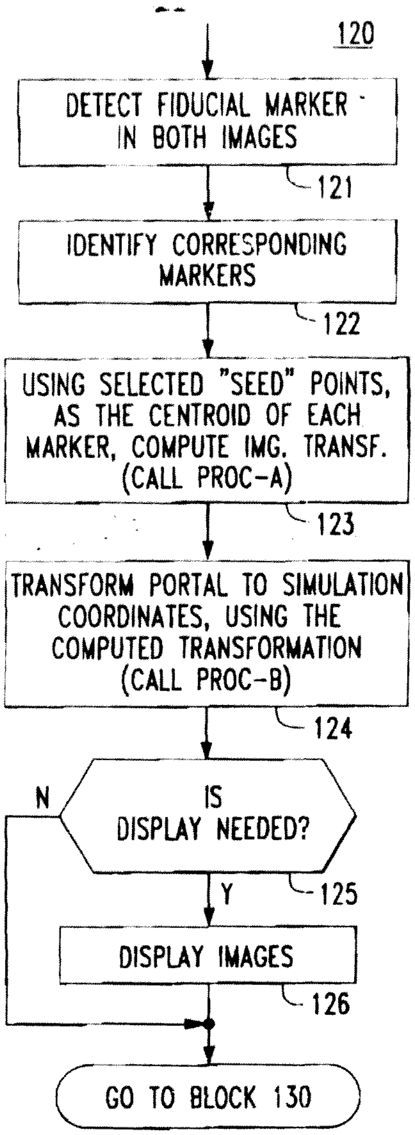

FIG. 7

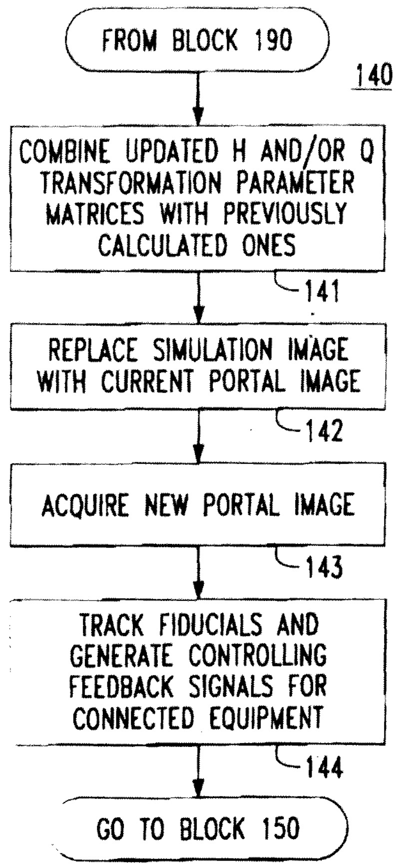

FIG. 11

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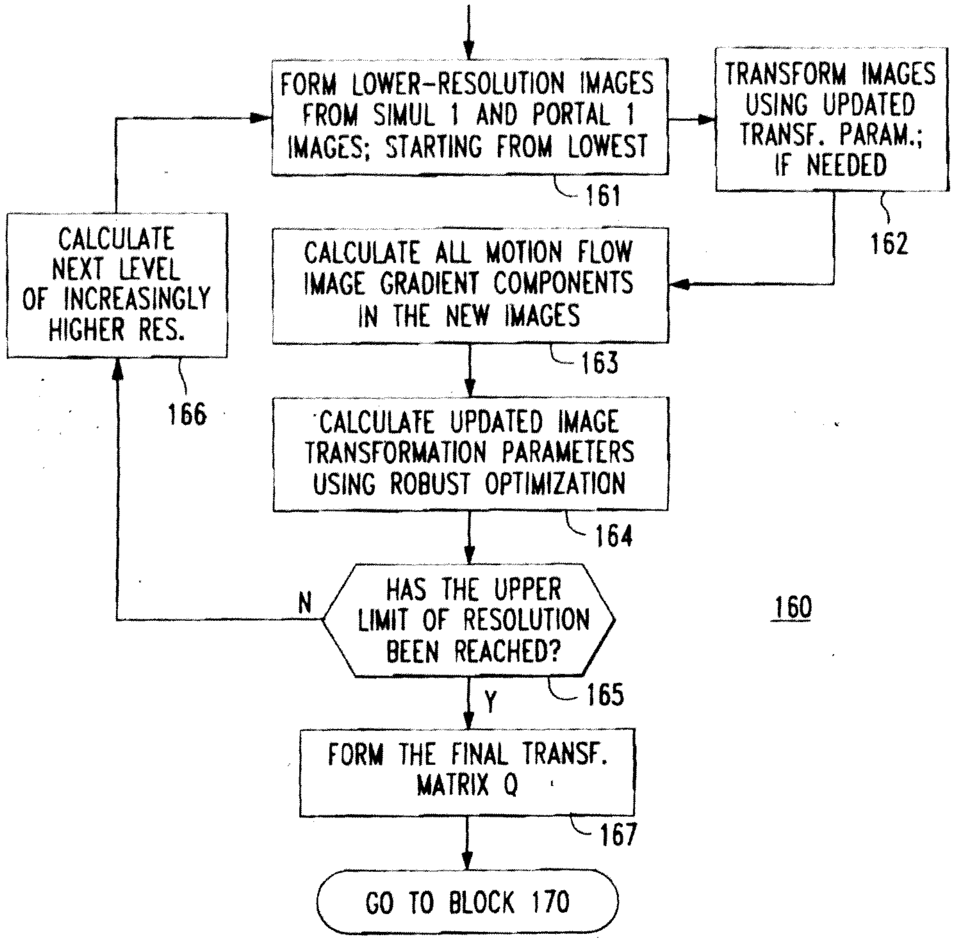

FIG. 9

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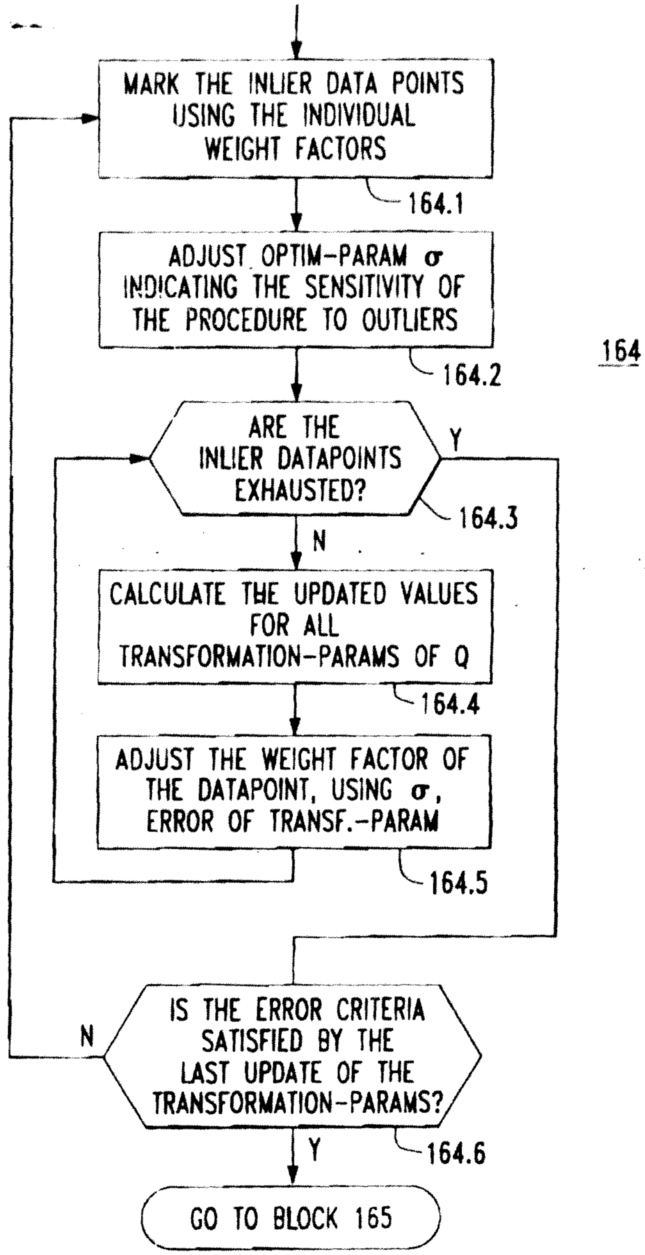

FIG. 10

EXHIBIT E

08/7...

MAIL ROOM SEP 19 1996

PATENT APPLICATION TRANSMITTAL LETTER

Case Docket No. 127444

ASSISTANT COMMISSIONER FOR PATENTS
Washington, D.C. 20231

Sir:

Transmitted herewith for filing is the patent application of
Inventors: Andre M. Kalend et al.
For: APPARATUS RESPONSIVE TO MOVEMENT OF A PATIENT DURING TREATMENT/DIAGNOSIS

Enclosed are:

☒ TWELVE (12) ____________ sheets of drawings.

☒ Recordation Form PTO-1595 and an assignment of the invention to UNIVERSITY OF PITTSBURGH

☐ A certified copy of a ________________ application.

☒ Declaration and Power of Attorney.

☒ A verified statement to establish small entity status under 37 CFR 1.9 and 37 CFR 1.27.

☐ Information Disclosure Statement and Form PTO-1449.

The filing fee has been calculated as shown below:

	(Col. 1)	(Col. 2)	SMALL ENTITY			OTHER THAN A SMALL ENTITY	
FOR:	NO. FILED	NO. EXTRA	RATE	FEE	OR	RATE	FEE
BASIC FEE:				$ 375	OR		$ 750
TOTAL CLAIMS	21-20 = 0	* - 0 -	x 11 =	$ 11	OR	x 22 =	$
INDEP. CLAIMS	2-3 = -0	* - 0 -	x 39 =	$	OR	x 78 =	$
0 MULTIPLE DEPENDENT CLAIM PRESENTED			+ 125 =	$	OR	+ 250 =	$
			TOTAL	$386.00	OR	TOTAL	$ 750

*If the difference in Col. 1 is less than zero, enter "0" in Col. 2.

☐ Please charge Deposit Account No. ____________ in the amount of $_______. A duplicate copy of this sheet is enclosed.

☒ A check in the amount of $386.00 to cover the filing fee is enclosed.

☐ The Commissioner is hereby authorized to charge payment of the following fees associated with this communication or credit any overpayment to Deposit Account No. ________. A duplicate copy of this sheet is enclosed.

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APPARATUS RESPONSIVE TO MOVEMENT ~~OF A PATIENT~~ DURING TREATMENT/DIAGNOSIS

BACKGROUND OF THE INVENTION

Field of the Invention

This invention relates to medical use of radiation for treatment and diagnosis, and more particularly to detection and response to patient movement during radiological treatment and diagnosis.

Background Information

Conventional radiotherapy treatment relies on simple patient setup techniques. These techniques use stationary and a limited number of radiation fields, which are often much wider than the tumor or volume, thus effectively compensating for the possibility of a tumor geometric miss. Consequently, a substantial amount of healthy tissue is irradiated and becomes a radio-biological dose limiting factor in tumor control.

Modern conformal dynamic radiotherapy attempts to overcome the above radio-biological limitation by tight-margin conformation of radiation dose distribution tailored to the three-dimensional tumor volume by the use of computer-control multi-beam conformal dynamic radio therapy (CCRT). Consequently, the accuracy in patient position, knowledge of the movement of a patient including substantial motion of internal organs such as with breathing is of primary importance. In addition to patient movement which would cause the tight beam to miss the tumor, it is important to be able to detect patient movement which could cause a collision between the patient and the linear accelerator, which is repeatedly repositioned to establish the multiple treatment beams.

There is a need therefore for apparatus for detecting patient movement on radiological treatments/diagnostic equipment.

There is a particular need for such apparatus which can detect sub-millimeter patient movement in real time.

There is also a need for such apparatus which can detect patient movement initiated from various treatment positions.

There is also a need for such apparatus which can detect patient movement under varying lighting conditions.

There is a further need for such apparatus which can discriminate movement associated with patient breathing from other movement and accommodate therefor.

SUMMARY OF THE INVENTION

These needs and others are satisfied by the invention which is directed to apparatus responsive to movement of a patient which identifies and tracks movement of at least one passive fiducial on the patient. The apparatus applies multiple levels of filtering which can include: correlation, preferably normalized correlation, sparse sampling, bracketing and interpolation, and minima suppression to rapidly identify the location of the at least one fiducial. The multiple levels of filtering are applied at multiple levels of resolution of the digital image signals.

Interest operators can be used in combination with templates to locate the positions of the passive fiducials. The templates can be selected interactively by a user from a display generated by the digital image signals. Alternatively, the template used for tracking is selected from images generated using an initial template. Rather than using the image which best matches the initial template, the template with a median match is selected.

As another aspect of the invention, the means generating an output includes means indicating movement of the at least one passive fiducial relative to at least one selected level of displacement. Preferably, the output means generates a warning that movement exceeds a first displacement and includes means providing a signal for terminating radiation treatment when the movement exceeds a second greater displacement. Preferably, the means providing an indication of movement includes a display generating an image of the patient and the fiducials, together with an indication of movement relative to the first and second displacements.

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As yet another aspect of the invention, the means determining movement of the passive fiducials includes means detecting movement associated with patient breathing and random movement. The movement associated with patient breathing can be used to generate a gating signal synchronized to patient breathing. This gating signal can then be used to actuate the beam generator only during selected parts of the breathing cycle.

BRIEF DESCRIPTION OF THE DRAWINGS

A full understanding of the invention can be gained from the following description of the preferred embodiments when read in conjunction with the accompanying drawings in which:

Figure 1 is an isometric view of apparatus in accordance with the invention for implementing conformal dynamic radiotherapy.

Figure 2 is a plan view of a patient reclining on a couch which forms part of the apparatus of Figure 1 and illustrating the placement of fiducials in accordance with the invention.

Figure 3 is a perspective view of a preferred fiducial used in implementation of the invention.

Figure 4 is a functional diagram illustrating implementation of the invention.

Figure 5 is an illustration of a display which is generated by the apparatus of Figure 1 in implementation of the invention.

Figures 6-16 are flow charts of software used in implementation of the invention.

Figure 17 is an illustration of an interest operator which can be used in implementation of the invention.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Figure 1 illustrates a radiotherapy treatment system 1 in which the invention is implemented. This system 1 includes a machine 3 having a gantry 5 pivotally mounted on a machine base 7 for rotation about a horizontal axis 9. The gantry 5 has a first arm 11 carrying a collimator 13 which directs a beam of high energy radiation 15, such as a beam of high energy photons, along a path which is perpendicular to and passes through an extension of the axis of rotation 9. This intersection is referred to as the isocenter 17. In some machines, a portal imager 19

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is mounted on a second arm 21 on the opposite end of the gantry in alignment with the radiation beam 15. The portal imager 19 records radiation which is not absorbed by the patient.

The isocenter 17 serves as the origin of a coordinate system for room space. As can be seen, the X axis coincides with the axis of rotation 9 of the gantry. Thus, as the gantry 5 rotates it defines a plane of treatment containing the Y and Z axes.

The machine 3 further includes a patient positioning assembly 23, which includes a couch 25 mounted on a support 27 for vertical, lateral and longitudinal movement relative to the support. The support 27 is mounted on a turntable 29, which has its axis 31 vertically aligned under the isocenter 17 and concentric with the Z axis. With this arrangement, the patient positioning assembly 23 has four degrees of freedom: translation in the X, Y and Z axes of room space and rotation about the Z axis. Thus, the patient is not rotated about the longitudinal axis of the couch or tilted about a horizontal axis extending transversely through the couch. However, with the addition of rotation of the gantry in the Y-Z treatment plane, the radiation beam 15 can be directed through a patient reclining on the couch 25 in any desired direction. A computer 33 controls movement of the patient positioning assembly 23 and the gantry 5 for establishing the progression of high energy treatment beams used in practicing conformal radiation therapy.

As previously discussed, in conformal radiation therapy the beam 15 is tightly conformed by the collimator 13 to the specific tumor to be treated. Thus, movement of the patient on the couch 25 of the patient position assembly 23 can cause misalignment of the radiation beam 15 with the tumor. This not only degrades treatment of the tumor but also exposes surrounding healthy tissue to unwanted levels of radiation. In addition, normal breathing by the patient can cause movement of internal organs by an amount which would result in misalignment of the beam. For instance, a tumor on the lower portion of the lung can move several centimeters during normal breathing. Slight movement of the patient can be tolerated; however, treatment should be terminated if acceptable tolerances of movement are exceeded. Furthermore, excessive movement by the patient can also cause a collision between the patient and the gantry as the patient positioning assembly 23 and gantry are positioned for successive treatment beams.

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The invention employs a vision system 34 to measure and respond to patient movement. The vision system 34 includes at least one video camera 35. Preferably, multiple cameras are used. In the exemplary embodiment of the invention a first camera 35_1 is mounted on the first arm 11 of the gantry 5 adjacent the collimator 13 and is aimed to capture an image of a patient 37 positioned on the couch 25, as shown in Figure 2. As the camera 35_1 will be below the couch 25 for some positions of the gantry 5, a second camera 35_2 is fixed to the ceiling over the patient positioning assembly 23. The field of view of this camera 35_2 will be blocked when the gantry 5 is at the top of its arc. Thus, the patient is visible to at least one camera 35 at all times. Additional cameras 35 could be provided, such as cameras laterally displaced from the patient positioning assembly 23 to provide more sensitivity to movement along the axis of, for instance, the camera 35_2. However, as will be discussed below, a single camera can detect three-dimensional movement, including movement toward and away from the camera which is detected as a change in the size of the image.

In the exemplary embodiment of the invention, natural or artificial fiducials are used to detect patient movement. Natural fiducials could be scars or other prominent features of the patient. The preferred fiducial 39 shown in Figure 3 is a sphere 41 covered with a material having a lambertian surface. Such a surface is highly reflective under low light conditions, yet provides a uniform scattered reflection with no highlights. The sphere 41 is attached to the center of a non-reflective base 43 which is secured to the patient's skin, such as by an adhesive.

In principle, only one fiducial 39 is required. As a practical matter, it is advantageous to provide multiple fiducials placed on the patient so as to detect any movement of the critical locations. Thus, as shown in Figure 2, by way of example, four fiducials 39 are placed on the patient's chest. Natural skin markings could be used in addition to the artificial fiducials shown in Figure 3. If more than one camera 35 is used, each tracks as many of the fiducials 39 as it can see.

Figure 4 is a functional diagram of the invention. The camera(s) 35 capture an image of the fiducials 39 on the patient 37 reclining on the patient positioning assembly 23. The image captured by the camera 35 is digitized by digitizer 45 to generate digital image signals. These digital image signals are 0 to 255 gray scale signals for each camera pixel. The digital image signals are processed by a processor which includes a ~~position~~ patient motion detector 47. ~~Position~~ Patient motion detector 47

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is implemented in the computer 49 shown in Figure 1. The computer 49 includes a monitor 51 which generates a display 53, an example of which is shown in Figure 5. The man machine interface 55 for the computer 49 includes a keyboard 57 and a pointing device 59, such as a mouse or trackball.

As will be discussed fully, the patient motion detector 47 detects and identifies the fiducials 39 and then tracks their movement. Movement within a certain narrow tolerance is acceptable, while larger movements are unacceptable. Visible and/or audio warnings of these two classifications of movement can be generated. A gating signal generator 61 responds to unacceptable movement to disable the beam generator 63. This unacceptable movement which would terminate the radiation beam can be movement which displaces the target tumor so that it is missed by the radiation beam, or could be movement which would cause a collision between the patient and the gantry 5 during movement of the machine from one treatment beam to the next. In the former case, the gating signal generator 61 could re-enable the beam generator, if the patient returns to the proper position. For instance, a large sigh could temporarily displace the target area by an unacceptable amount. In accordance with another aspect of the invention, the patient motion detector 47 can track patient breathing and extract such quasi-periodic motion from random patient motion. Gating of the beam generator can then be synchronized with patient breathing. For instance, a tumor on the lung could move up to 4 to 5 centimeters during patient breathing. This is an unacceptable amount of movement. However, by synchronizing generation of the radiation beam with breathing, the tumor can be repetitively irradiated at a fixed position during the breathing cycle.

As shown in Figure 5, the display 53 presents an image of the patient 37 with the fiducials 39 appearing prominently. An indicator 65, such as the square shown, surrounds each fiducial and is color coded to indicate the state of motion of the fiducial. The fiducial with the largest displacement such as 39a is singled out by a distinctive marker, such as a red square 65a, while the remaining markers are green squares in the exemplary system. The display also includes a traffic light 67 having a green section 67g, a yellow section 67y and a red section 67r. When motion of the fiducials is within preferred tolerances, the green section 67g of the traffic light is on. For motion which is outside the normal range, but which is still acceptable, the yellow section 67y is on. The traffic light turns red when the motion of any of the fiducials

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is approaching the unacceptable. A scale 69 along the side of the display 53 indicates in bar graph form the percentage of maximum allowable displacement of the fiducial of maximum displacement. Thus, for instance, if the red light 67r is illuminated and the bar graph 71 indicates 80%, the fiducial with maximum displacement has moved by a distance which is four fifths of the way through the acceptable displacement. The green, yellow and red regions need not be equal as shown in the example.

Detection of motion of a patient using passive fiducials requires an implementation which is robust enough to accommodate for the variations in the shapes, appearance and lighting conditions to which the fiducials are subjected and, at the same time, is fast enough to provide real time tracking of patient movement. The invention satisfies these requirements by utilization of successive levels of filtering and templates which are modified to accommodate for actual conditions. The result is a system which can track patient movement at 20 Hz or better.

Flow charts of suitable software 100 for implementing the invention are illustrated in Figures 6-16. Figure 6 illustrates the main routine of the software 100 and includes detecting fiducials on the patient's body is in the current camera image at 110. As will be described, this is accomplished utilizing templates. The templates are then fine tuned at 120 for the specific patient and environmental conditions. As long as the user desires monitoring as determined at 130, a loop is entered in which each individual fiducial is tracked as indicated at 140. It is possible that a fiducial can be lost by the tracking system. This could occur, for instance, if the patient moves so that a fiducial is blocked from the camera's view, or the patient moves a hand through the line of sight of the camera. Also, a fiducial may be temporarily lost by rapid movement or adverse lighting conditions. If a fiducial is lost, as determined at 150, a number of attempts can be made to reacquire it. If the fiducial is not reacquired within a reasonable time, however, it is removed from tracking as indicated by 160 and 170. If the selected number of attempts to reacquire, such as for example, five, have not been reached, an attempt is made to reacquire the fiducial at 180. If the fiducial is reacquired at 190, then a routine is run at 200 to generate any alarm if needed, and gating signals for the accelerator or beam generator 63 as indicated at 200. As long as any fiducials remain to be tracked as indicated at 210, the tracking loop is repetitively run.

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Figure 7 illustrates the general routine 110 for detecting the fiducials 39 in the image represented by the digital image signals. As mentioned, templates are used to identify the locations of the fiducials. The templates indicate what the pattern of digital signals representing the fiducial should look like. The size of the templates used must be considered. Larger templates improve the accuracy but take longer to process. In the exemplary system, templates 40 pixels square have been utilized. There are several ways in which the templates can be generated. As indicated at 111 in Figure 7, idealized image templates can be utilized. In addition to such idealized templates or in place thereof, pre-stored image templates for the patient can be used as indicated at 112. Such pre-stored templates are used, for instance, for natural fiducials such as scars. One template is used for each family of fiducials. For instance, if all of the fiducials are the preferred fiducials such as shown in Figure 3, only one template is required because all of the fiducials in the family will generate a similar image.

In addition, templates can be selected interactively by the user at 113. This is accomplished by using the mouse or trackball 59 to click on the center of a representation of the fiducial on the display 53.

Where the idealized or pre-stored templates are utilized, a multi-resolution pyramid is used to locate the fiducials in the image using the templates. Thus, as indicated at 114, a search is made of the current image in low resolution for candidate matches of all template families. In the exemplary embodiment of the invention, one-third resolution is used at this point. Matches are made using a normalized correlation between the template and the image. The matches found in low resolution are then verified and localized in high resolution at 115. The K best matches are then selected as the most reliable fiducials at 116 where K equals the number of fiducials to be tracked. The user is then given the opportunity at 117 to edit the detected location of fiducials found either through use of the idealized or pre-stored templates or templates generated interactively.

The details of the low resolution detection routine performed in block 114 of Figure 7 is shown in Figure 8. As shown at 114.1, the image can be raster scanned selecting points using sparse sampling. In raster scanning pixels are considered successively along each line, line-by-line in increments of one, while in sparse sampling the increment is greater than one. Alternatively, the image can be

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raster scanned as indicated at 114.2, selecting candidate points using interest operators followed by thresholding. Interest operators are simple patterns which emphasize gray scale characteristics of a particular fiducial. An example is shown in Figure 17, where the fiducial is a light circle 73 on a dark background 75. The interest operator 77 could be, for instance, the one pixel value 79 in the center having a gray scale value matching that of the light circle 73, and the four pixels 81 at the cardinal points having gray scale values similar to that of the background 75. Such interest operators permit rapid searching of the image and should be selected as to assure identifying all of the fiducials in the family. They will most likely also generate additional candidate points. Returning to Figure 8, the interest operator generated value in the exemplary system is the relative albedo. The relative albedo of each point in the low resolution scan is compared to a threshold value to select candidate points.

For each candidate point, a template matching is performed at 114.3, using a normalized correlation. Unwanted point matches are then filtered out at 114.4 using thresholding on the normalized correlation value. In the exemplary embodiment, a normalized correlation of 0.75 was used as the threshold. Bracketing and interpolation are then used at 114.5 to localize the remaining point/matches. In implementing bracketing, a rectangular image window is selected within which the desired point match will definitely lie. Then by interpolating between the correlation values of points on the border of the selected window along with its center, a new estimate of the location of the point match is calculated. This process is repeated with successively smaller windows centered on the new estimate of the location of the point match until a singular point is reached. In the exemplary system, the interpolation is performed using a two-dimensional Gaussian distribution.

Figure 9 illustrates the techniques for verifying the candidate matches in high-resolution indicated at 115 in Figure 7. Bracketing is performed on the selected matches in high resolution as indicated at 115.1. These points are then filtered at 115.2 within the same image neighborhood using minima suppression. In implementing minima suppression, for each point which has been a match, an area the size of the template is centered on the point. A point is selected as a further candidate match only if it is the best correlation with the template within the template window.

An important aspect of the invention is the fine tuning of the tracking templates called for at 120 in Figure 6. Figure 10 illustrates the details of fine tuning

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the templates. As indicated at 121, the median point/match from fiducials detected using the same initial template is selected. For example, if there are three point matches for a fiducial family, the match having the middle value of correlation is selected. Notice that the match with the best correlation is not selected as it is likely to eliminate some valid matches. This technique adapts the selection of the template to be used for tracking to the actual conditions existing at the time of the selection. The relevant image portion is then acquired as the new template at 122, and the position, the interest operator value and the normalized correlation for all relevant point/matches using this newly acquired template is then recorded at 123. The steps 121-123 are accomplished for each template family. Then, the current spacial pattern of all the fiducials determined by the point/matches, is recorded at 124.

The program then enters the tracking loop at block 130 in Figure 6. The routine for continuous tracking, which is called at 140 in Figure 6 is illustrated in Figure 11. The new position of the fiducial is estimated at 131 by projecting a velocity vector calculated from prior positions of the fiducial. Localization of fiducial position is then implemented in low resolution using bracketing and interpolation as indicated at 132. This is followed by high resolution localization of the fiducial position at 133, also using bracketing and interpolation.

The low resolution localization of block 131 is implemented by the routine illustrated in Figure 12. As indicated at 132.1 points are selected by raster scanning the image window using sparse sampling. If interest operators are used, the interest operators with the value closest to that of the fiducial in the previous tracking step is selected at 132.2. In either case, a best match is selected using normalized correlation template matching at 132.3. This is followed by bracketing on the position of the best match at 132.4.

Figure 13 illustrates the high resolution localization of fiducials called for in block 133 of Figure 11. As indicated, bracketing is performed on a candidate with best match in high resolution as indicated at 133.1. If a match is found, the normalized correlation, interest operator value and position of the best match are calculated at 133.2. If desired, the sub-pixel accuracy of the position can be calculated at 133.3. The same interpolation technique as in bracketing and interpolation, as described above, is used. Alternatively, bilinear interpolation between the surrounding pixel correlation values could be used. Finally, if needed, charge coupled device

(CCD) jitter is filtered out of the position at 133.4. In the exemplary system, a low pass filter is used.

The lost fiducial routine 150 in Figure 6 is shown in Figure 14. If the tracking routine finds no fiducial within the specified image window at 151, then clearly the fiducial has been lost. Even if a fiducial has been found, confirmation must be made that it is in fact the new position of the fiducial. Hence, a number of constancy tests are applied in 152. For instance, the normalized correlation value and the interest operator value must not change by more than a selected amount, such as, for example, 15%, from the most current values. Also, image limits are applied. For instance, the fiducial should not have changed position by more than a predetermined amount or, if the edge of the image is reached, the position indicated is not accepted as the fiducial may be out of the field of view, although a continued indication that it is at the edge may be presented.

The routine 180 in Figure 6 for reacquiring the lost fiducial is shown in Figure 15. First, the new position of the fiducial is estimated at 181 using a larger search window than was used at 141 in Figure 11. The image window is then raster scanned in high resolution using sparse sampling to select the best match, if any, at 182. Bracketing is then performed around the position of the best match, if any, at 183. The normalized correlation interest operator albedo and the position of the fiducial best matched is then determined at 184. This is followed by calculation of sub-pixel accuracy, if needed, at 185. Finally, the number of successive attempts to reacquire the fiducial is updated at 186.

Figure 16 illustrates the routine 200 in Figure 6 for generating the alarms and gating the accelerator or beam generator. The direction and distance traveled by each currently actively tracked fiducial since the detection step is estimated at 201. The spacial pattern of the actively tracked fiducials is compared with the initial pattern and previous patterns at 202. Any quasi-periodic motion associated with the individual fiducials and/or the spacial pattern is predicted at 203 such as by using past data analysis. This would include movement associated with breathing or tremor of the patient. The alarm warnings, alarm states and accelerator gating signals are then computed at 204 for display or for feedback to the equipment, such as the accelerator.

While specific embodiments of the invention have been described in detail, it will be appreciated by those skilled in the art that various modifications and

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alternatives to those details could be developed in light of the overall teachings of the disclosure. Accordingly, the particular arrangements disclosed are meant to be illustrative only and not limiting as to the scope of invention which is to be given the full breadth of the claims appended and any and all equivalents thereof.

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<u>What is Claimed is:</u>

1. Apparatus responsive to movement of a patient positioned on a patient positioning assembly during treatment/diagnosis, said apparatus comprising:

camera means generating digital image signals representing an image of at least one passive fiducial having a lambertian surface on said patient; and

processing means comprising means responsive to actual shape, appearance and lighting conditions of said at least one passive fiducial having a lambertian surface ~~and~~ in said image represented by said digital image signals to determine successive positions of said at least one passive fiducial having a lambertian surface, means repetitively determining movement of said at least one passive fiducial having a lambertian surface from said successive positions, and means generating an output in response to predetermined values of said movement.

14/~~2~~. The apparatus of Claim ~~1~~ ~~23~~ 13, wherein said means generating an output includes means generating an indication of movement relative to at least one selected level of displacement.

15/~~3~~. The apparatus of Claim ~~2~~ 14, wherein said means generating said indication of movement includes means providing a warning that said movement exceeds a first displacement and means providing a signal for terminating radiation treatment/diagnosis ~~treatment~~ when said movement exceeds a second displacement greater than said first displacement.

16/~~4~~. The apparatus of Claim ~~2~~ 14, wherein said means generating an indication of movement comprises display means generating an image of said fiducials and an indication of said movement relative to said first and second displacements.

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17 ~~5.~~ The apparatus of Claim 16 ~~4,~~ wherein said camera means includes means generating digital image signals for a plurality of fiducials, said means repetitively determining movement determines movement of each of said plurality of fiducials, and said display means includes indicator means indicating a fiducial with the greatest movement.

18 ~~6.~~ The apparatus of Claim 14 ~~7~~, wherein said means repetitively determining movement includes means detecting movement associated with patient breathing and random movement, and wherein said means generating an indication of movement indicates said random movement.

3 ~~7.~~ The apparatus of Claim ~~22~~ 2 ~~1,~~ wherein said means repetitively determining movement of said at least one ~~passive~~ fiducial includes means detecting movement associated with patient breathing, and said output means comprises means generating a gating signal synchronized to said patient breathing.

4 ~~8.~~ The apparatus of Claim ~~22~~ 2 ~~1,~~ wherein said processing means comprises means repetitively applying multiple levels of filtering to said digital image signals to determine successive positions of said at least one ~~passive~~ fiducial.

5 ~~9.~~ The apparatus of Claim 4 ~~8~~, wherein said means applying multiple levels of filtering includes means applying bracketing and interpolation to said digital image signals to determine position of said at least one fiducial.

6 ~~10.~~ The apparatus of Claim 4 ~~8~~, wherein said means applying multiple levels of filtering includes means applying minima suppression to said digital image signals.

7 ~~11.~~ The apparatus of Claim 4 ~~8~~, wherein said means applying multiple levels of filtering include means applying at least two types of filtering selected from a group consisting of correlation, sparse sampling, bracketing and interpolation, and minima suppression.

8 ~~12.~~ The apparatus of Claim 7 ~~11~~, wherein said processing means includes means using multiple levels of resolution of said digital image signals to determine successive positions of at least one ~~passive~~ fiducial and said means applying multiple levels of filtering comprise means applying filtering at each of said multiple levels of resolution.

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9 ~~13~~. The apparatus of Claim ~~8~~ 4, wherein said processing means includes means using at least one of templates and interest operators to determine successive positions of said at least one fiducial from said digital image signals.

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10 ~~14~~. The apparatus of Claim ~~1~~ or 2, wherein said processing means comprises means using a template to successively determine position of said at least one ~~passive~~ fiducial and means selecting said template.

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15. The apparatus of Claim 14, wherein said means selecting said template includes a display means, means generating on said display means an image of said at least one passive fiducial from said digital image signals and user interface means for selection of a template from said image of said at least one passive fiducial.

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11 ~~16~~. The apparatus of Claim ~~14~~ 10, wherein said at least one ~~passive~~ fiducial comprises a plurality of ~~passive~~ fiducials, and said means selecting a template includes means generating an initial template, means generating template matches for each of said plurality of ~~passive~~ fiducials from said digital image signals using said initial template, and means selecting one of said template matches for use in determining positions of each of said plurality of fiducials.

12 ~~17~~. The apparatus of Claim ~~16~~ 11, wherein said means selecting said one of said template matches includes means generating a value for each of said templates matches, and means selecting a template match having a median value as said one template match.

18. The apparatus of Claim 1 wherein said at least one passive fiducial comprises a fiducial having ~~a~~ a lambertian surface.

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19. Apparatus responsive to movement of a patient positioned on a patient positioning assembly, said apparatus comprising:

camera means generating digital image signals representative of an image of said patient; and

processing means comprising means determining movement of said patient from said digital image signals, including movement associated with breathing by said patient, and gating means generating gating signals synchronized with said movement associated with breathing by said patient for actuating said beam generating means in synchronism with patient breathing.

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21 ~~20.~~ The apparatus of Claim ~~19~~ 20, wherein said camera means generates said digital image signals representing an image of at least one fiducial on said patient, and said means determining movement of said patient includes means determining movement of said at least one fiducial.

22 ~~21.~~ The apparatus of Claim ~~19~~ 20 adapted for use during treatment of said patient with a radiation beam generated by a beam generator, wherein said gating means comprises means generating said gating signals synchronized to actuate said beam generator in synchronism with patient breathing.

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ABSTRACT OF THE DISCLOSURE

A camera generates digital image signals representing an image of one or more natural or artificial fiducials on a patient positioned on treatment or diagnosis equipment. A processor applies multiple levels of filtering at multiple levels of resolution to repetitively determine successive fiducial positions. A warning signal is generated if movement exceeds certain limits but is still acceptable for treatment. Unacceptable displacement results in termination of the treatment beam. Tracking templates can be generated interactively from a display of the digital image signals or through automatic selection of an image having the median correlation to an initial template. A gating signal synchronized to patient breathing can be extracted from the digital image signals for controlling the radiation beam generator.

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VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS
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by inventor(s) Andre M. Kalend, Joel Greenberger, Karun B. Shimoga, Charalambos N. Athannassiou and Takeo Kanade
described in
[x] the specification filed herewith
[ ] application Serial No. ______, filed ______
[ ] Patent No. ______, issued ______

I hereby declare that rights under contract or law have been conveyed to and remain with the nonprofit organization with regard to the above-identified invention.

If the rights held by the nonprofit organization are not exclusive, each individual, concern or organization having rights to the invention is listed below* and no rights to the invention are held by any person, other than the inventor, who could not qualify as a small business concern under 37 CFR 1.9(d) or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e). *NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

NAME
ADDRESS
[ ] INDIVIDUAL [ ] SMALL BUSINESS CONCERN [ ] NONPROFIT ORGANIZATION

NAME
ADDRESS
[ ] INDIVIDUAL [ ] SMALL BUSINESS CONCERN [ ] NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF PERSON SIGNING FRANCES J. CONNELL
TITLE IN ORGANIZATION Director of Office of Intellectual Property
ADDRESS OF PERSON SIGNING 911 William Pitt Union, Pittsburgh, PA 15260
X Frances J. Connell DATE September 11, 1996

DECLARATION FOR PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled **APPARATUS RESPONSIVE TO MOVEMENT OF A PATIENT DURING TREATMENT/DIAGNOSIS** the specification of which (check one)

_X_ is attached hereto.
____ was filed on __________________ as Application Serial No. ____________
and was amended on __________________.
(if applicable)

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, §1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application[s] for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

PRIOR FOREIGN APPLICATION(S)

			Priority claimed	
NONE				
(Number)	(Country)	(Day/month/year filed)	Yes	No
(Number)	(Country)	(Day/month/year filed)	Yes	No
(Number)	(Country)	(Day/month/year filed)	Yes	No

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application[s] listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose to the United States Patent and

Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, §1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application:

NONE
(Application Serial No.) (Filing Date) (Status--patented, pending, abandoned)

(Application Serial No.) (Filing Date) (Status--patented, pending, abandoned)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

I hereby appoint Walter J. Blenko, Jr., Registration No. 18,526; Arnold B. Silverman, Registration No. 22,614; Richard V. Westerhoff, Registration No. 24,454; Lewis F. Gould, Jr., Registration No. 25,057; Stephan P. Gribok, Registration No. 29,643; Frederick A. Tecce, Registration No. 32,065; ~~Alan G. Towner, Registration No. 32,949;~~ David V. Radack, Registration No. 33,442; Kirk D. Houser, Registration No. 37,357; Richard P. Gilly, Registration No. 37,630; Diane R. Meyers, Registration No. 38,968; and Daniel S. Goldberg, Registration No. 39,689, as my attorneys or agents with full power of substitution and revocation, to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith, to amend the specification, to appeal in case of rejection, as they may deem advisable, to receive the patent when granted and generally to do all matters and things needful in the premises as fully and to all intents and purposes as I could do.

Please direct all correspondence to: Richard V. Westerhoff
Eckert Seamans Cherin & Mellott, 600 Grant Street, Forty-second Floor, Pittsburgh, Pennsylvania 15219, (412) 566-6000.

1-00
Full name of sole or first joint inventor **Andre M. Kalend**
Inventor's signature Date 8 27 96
Residence **Monroeville, PA**
Citizenship **Zaire**
Post Office Address **103 Trotwood Drive, Monroeville, PA 15146**

2-00
Full name of second joint inventor, if any **Joel Greenberger** 8/28/96
Inventor's signature Date
Residence **Sewickley, PA**
Citizenship **United States of America**
Post Office Address **749 Chestnut Street, Sewickley, PA 15143**

3 00

Full name of third joint inventor, if any Karun B. Shimoga
Inventor's signature [signature] Date Aug 13, '96
Residence Pittsburgh, PA
Citizenship India
Post Office Address 5030 Centre Avenue, Apt. #560, Pittsburgh, PA 15213

4 00

Full name of fourth joint inventor, if any Charalambos N. Athanassiou
Inventor's signature [signature] Date Aug 13, 96
Residence Pittsburgh, PA
Citizenship Greece
Post Office Address 515 S. Aiken Ave., Apt. #711, Pittsburgh, PA 15232

5 00

Full name of fifth joint inventor, if any Takeo Kanade
Inventor's signature T. Kanade Date Aug. 26, 1996
Residence Pittsburgh, PA
Citizenship Japan
Post Office Address 130 Penrose Dr., Pittsburgh, PA 15208

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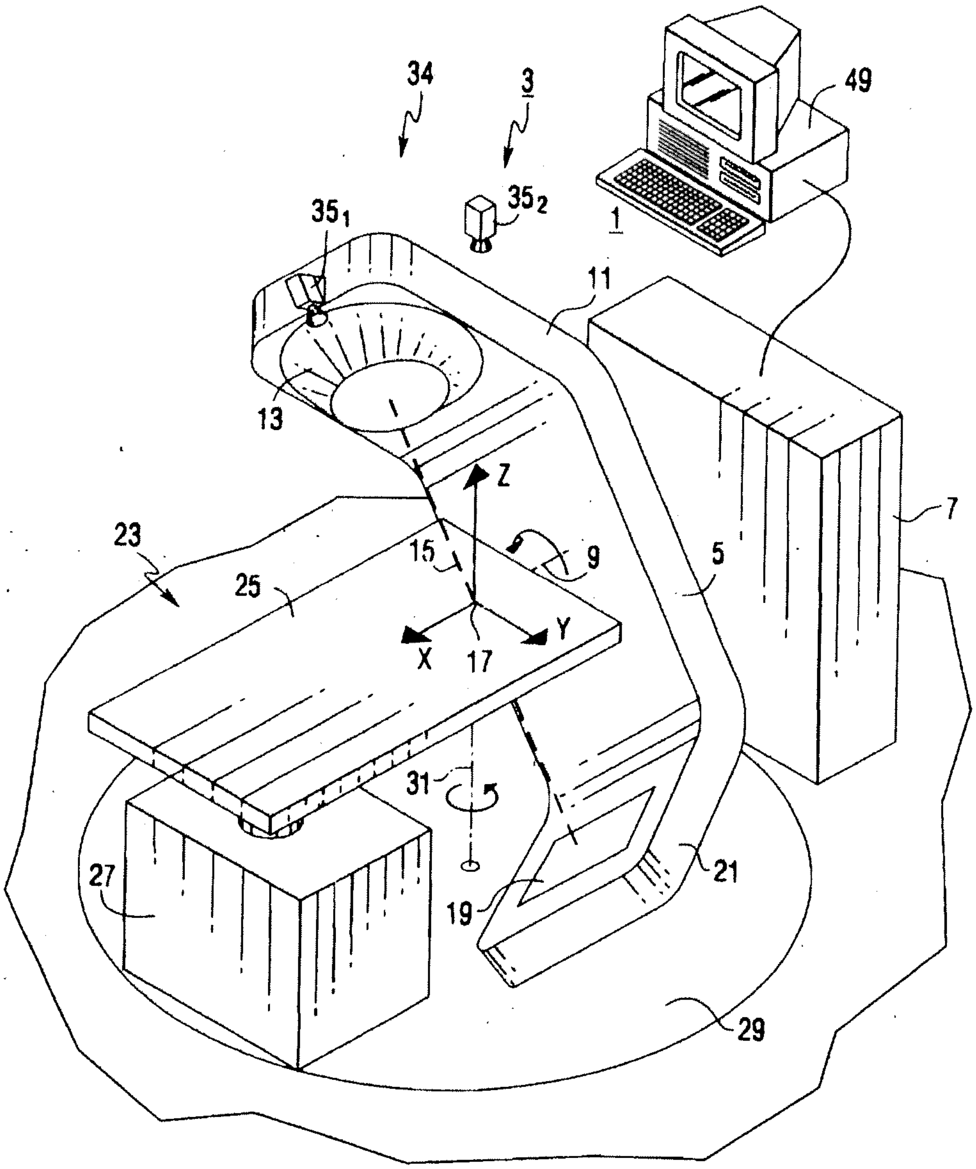

FIG. 1

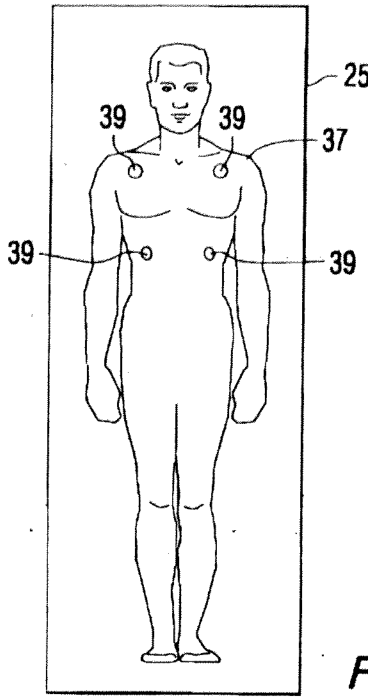

FIG. 2

PERFORM BRACKETING ON SELECTED POINT/MATCHES IN HI-RES IMAGE

115.1

115

FILTER SECONDARY MATCHES/POINTS WITHIN THE SAME IMAGE NEIGHBORHOOD USING MIN-SUPPRESSION

115.2

GO TO BLOCK 116

FIG. 9

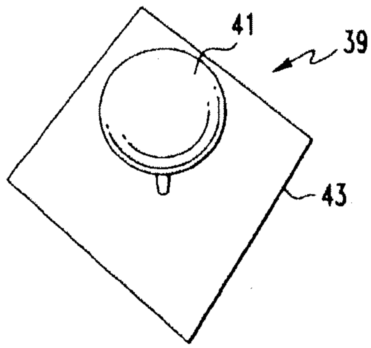
41
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FIG. 3

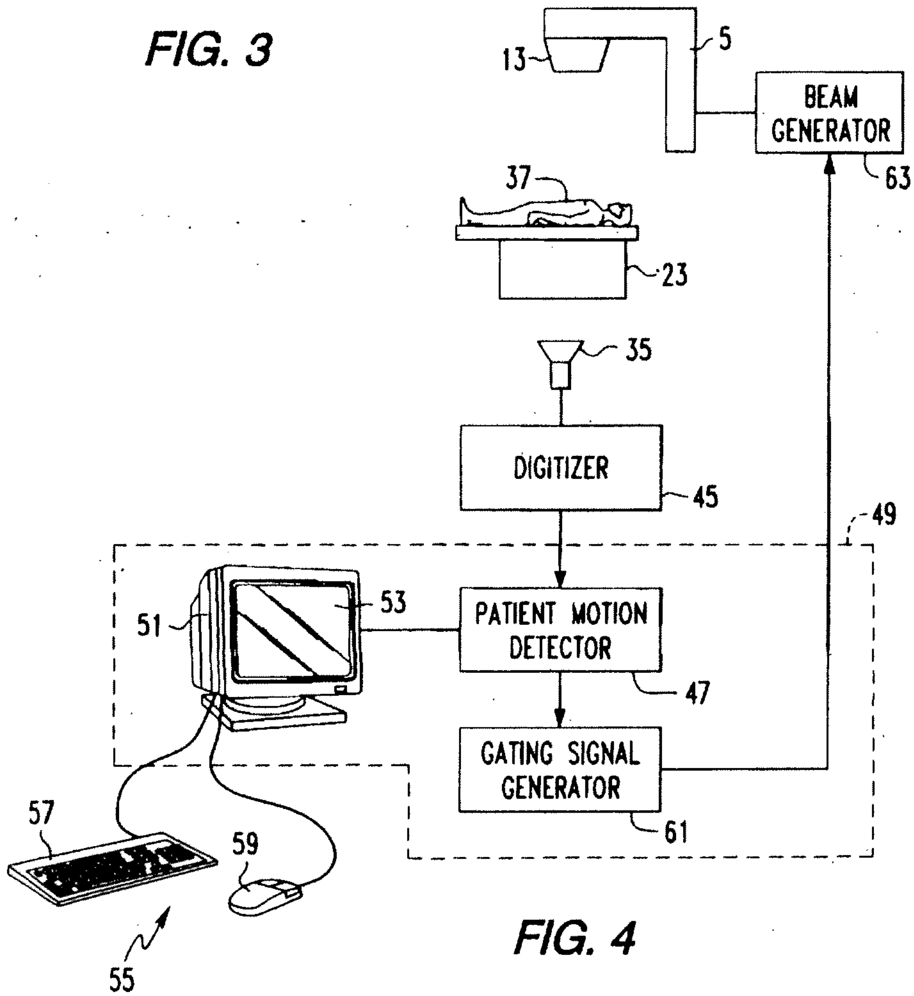
13
5
BEAM GENERATOR
63
37
23
35
DIGITIZER
45
49
51
53
PATIENT MOTION DETECTOR
47
GATING SIGNAL GENERATOR
61
57
59
55

FIG. 4

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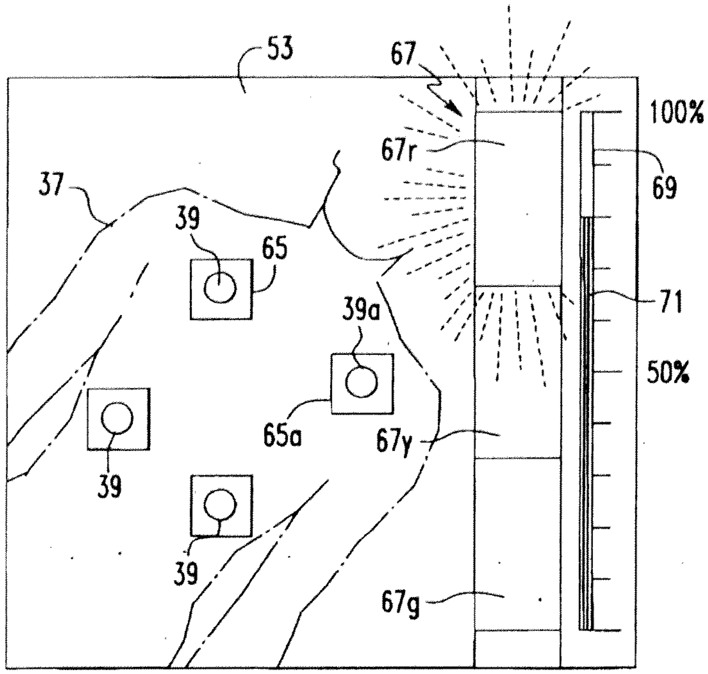

FIG. 5

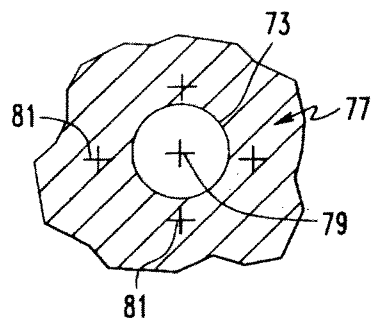

FIG. 17

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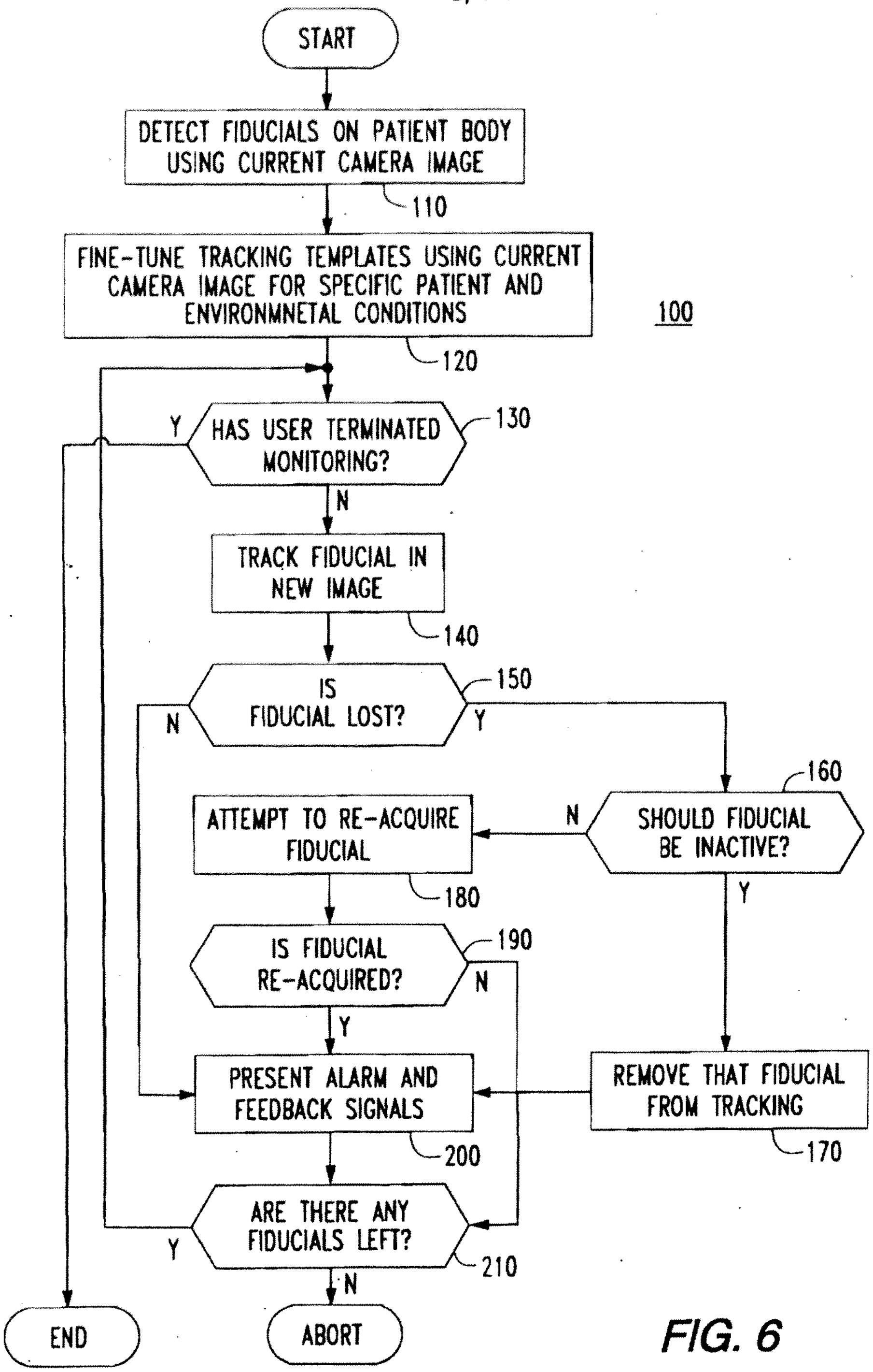

FIG. 6

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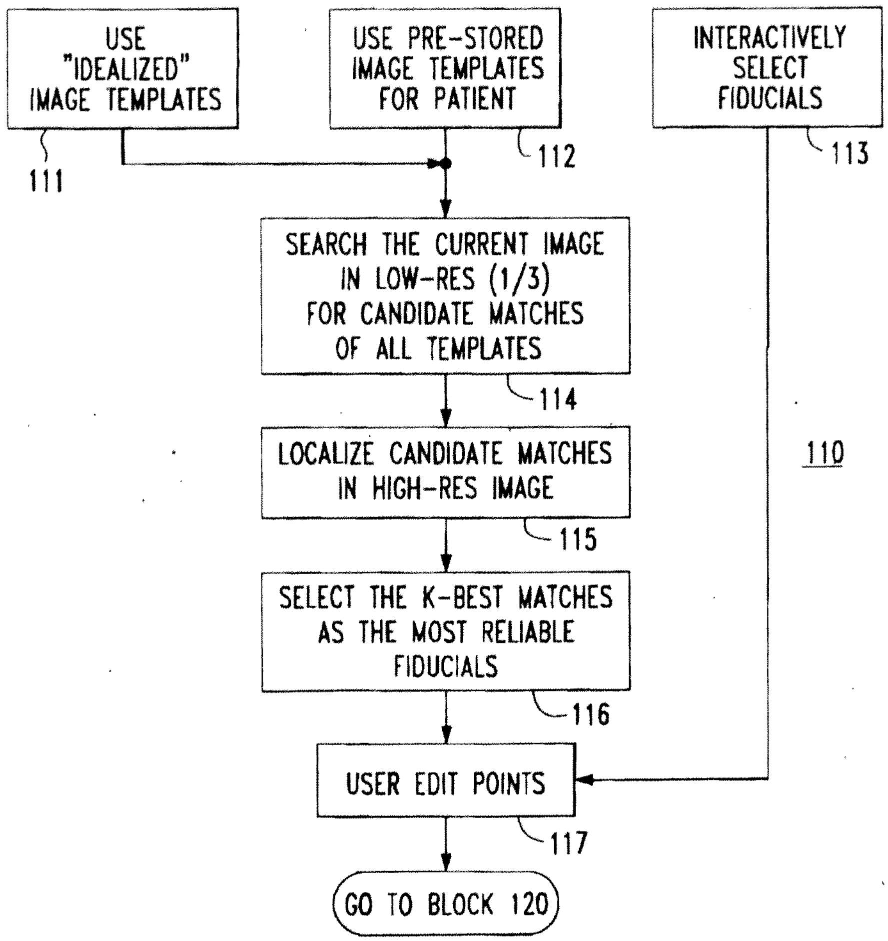

FIG. 7

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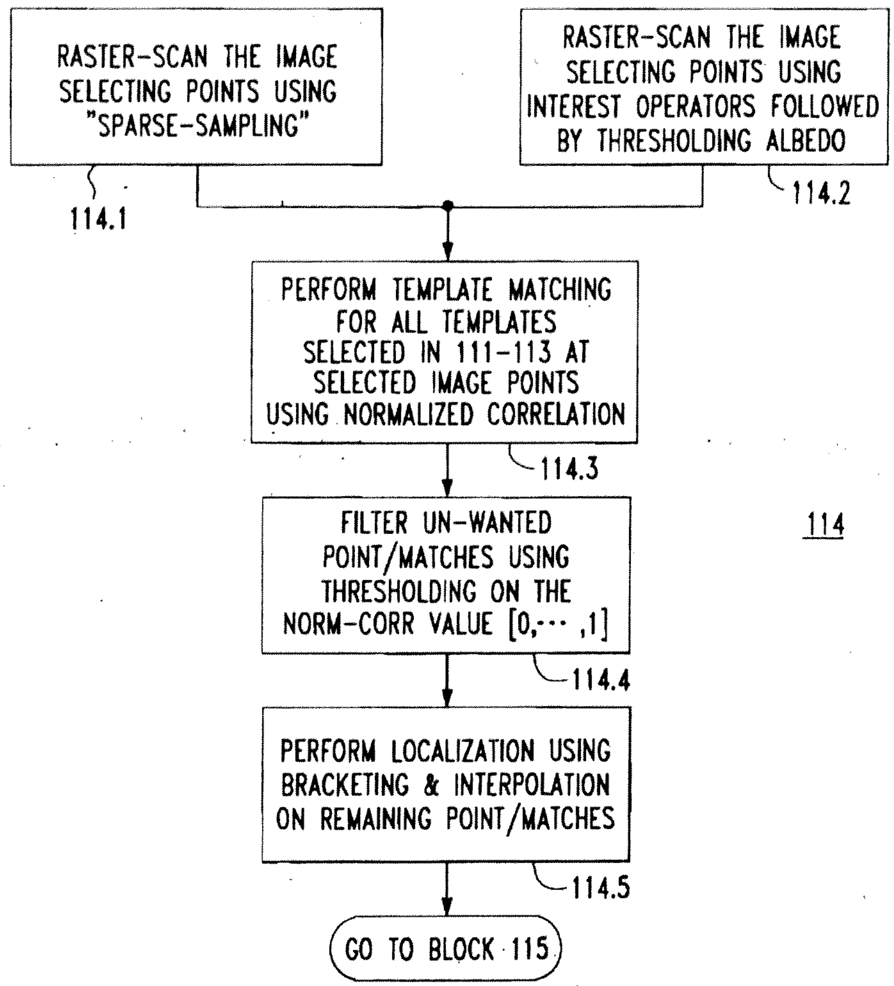

FIG. 8

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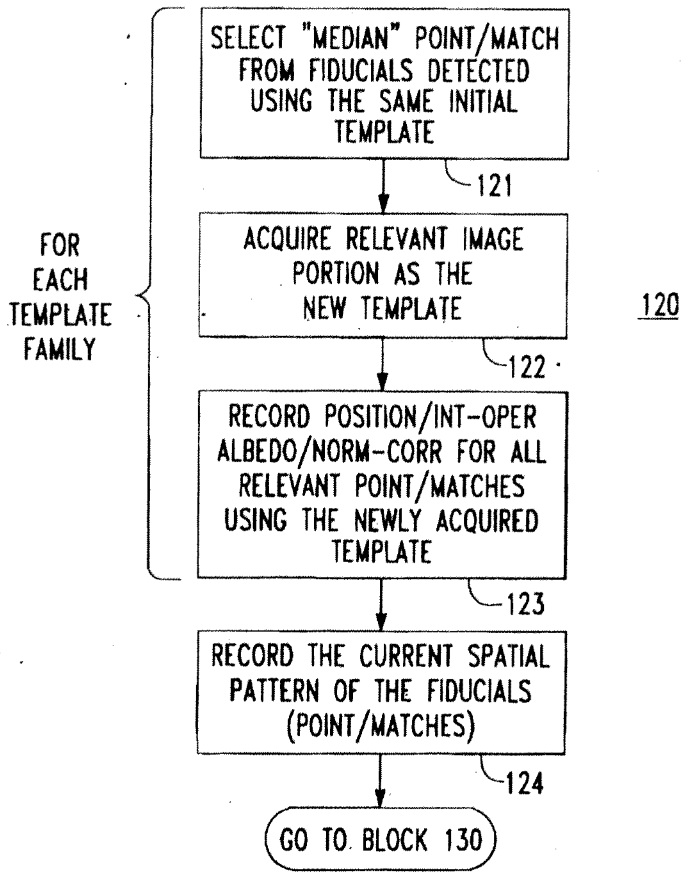

FIG. 10

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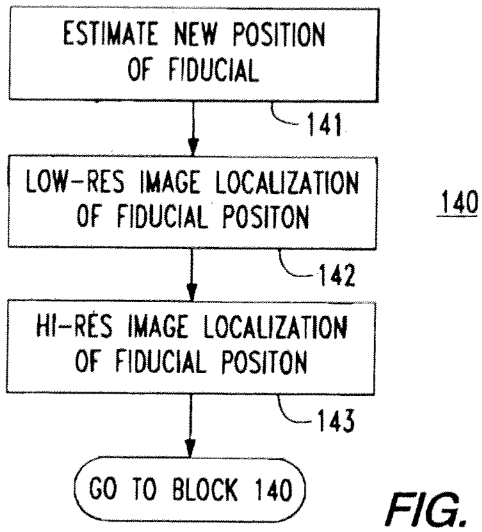

FIG. 11

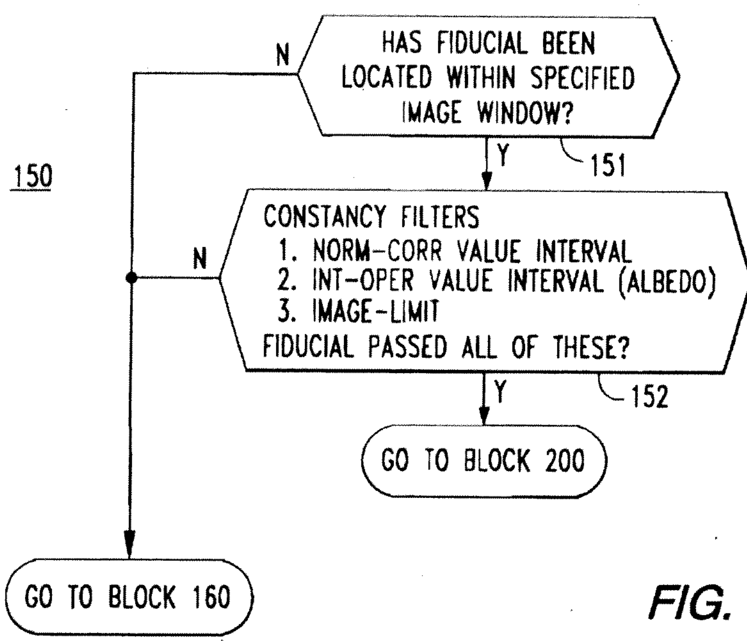

FIG. 14

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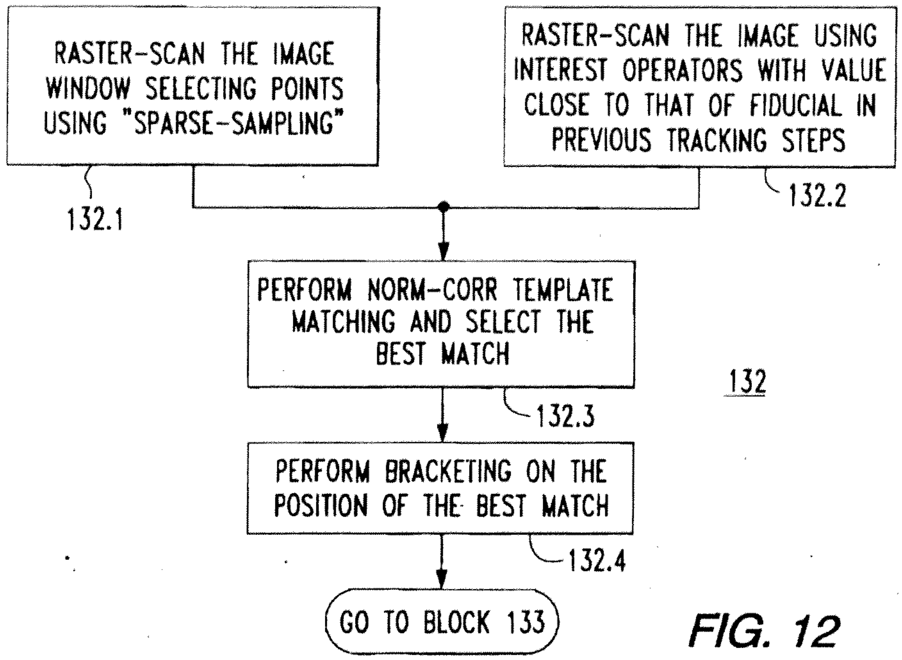

FIG. 12

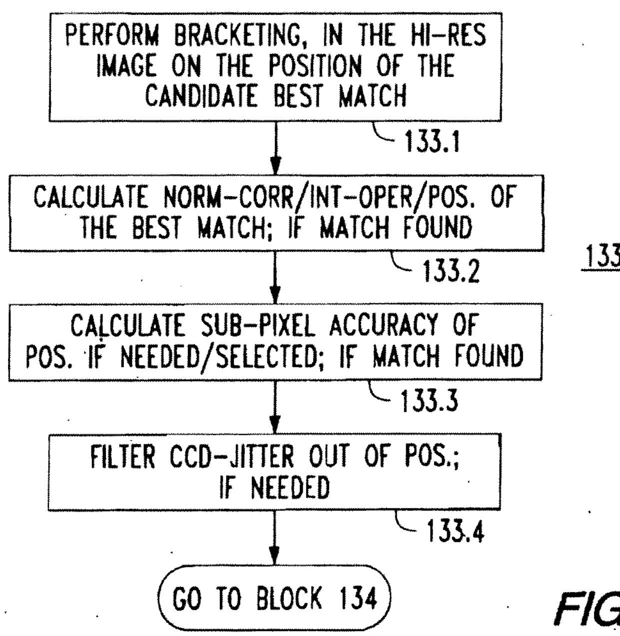

FIG. 13

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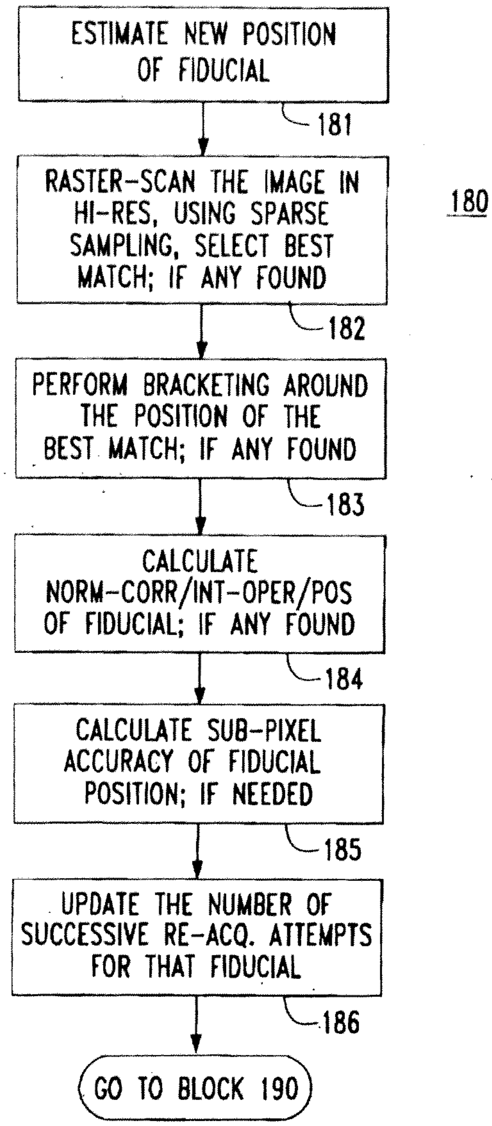

FIG. 15

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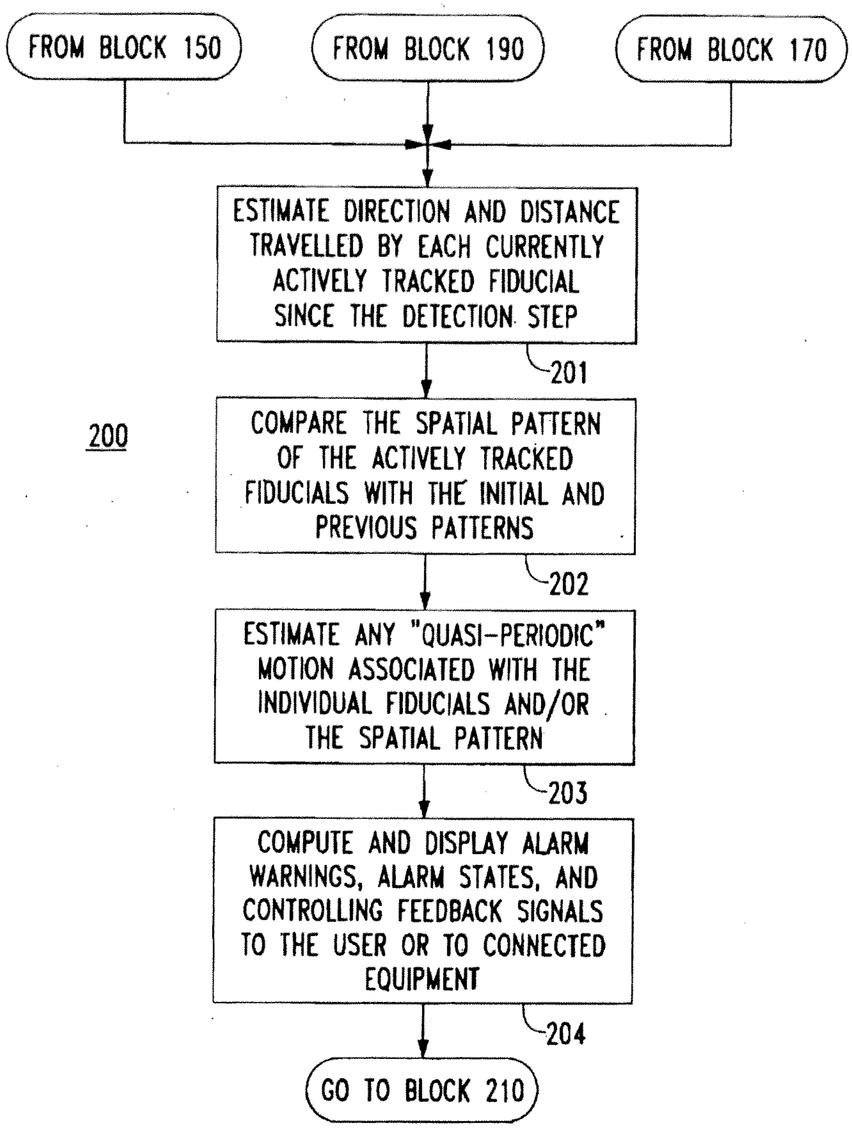

FIG. 16

PATENT APPLICATION SERIAL NO. 08/715834

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE
FEE RECORD SHEET

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PTO-1556
(5/87)

EXHIBIT F

IN THE UNITED STATES DISTRICT COURT

FOR THE WESTERN DISTRICT OF PENNSYLVANIA

- - -

UNIVERSITY OF PITTSBURGH,	)
Plaintiff,	)
vs.	) No. 2:07CV00491AJS
VARIAN MEDICAL SYSTEMS, INC.,	)
Defendant.	)

- - -

Videotape deposition of PETER MUNRO, Ph.D.

Thursday, October 18, 2007

- - -

The videotape deposition of PETER MUNRO, Ph.D., called as a witness by the plaintiff, pursuant to notice and the Federal Rules of Civil Procedure pertaining to the taking of depositions, taken before me, the undersigned, Lance E. Hannaford, a Notary Public in and for the Commonwealth of Pennsylvania, at the offices of Morgan Lewis, 32nd Floor, One Oxford Centre, Pittsburgh, Pennsylvania 15222, commencing at 8:58 o'clock a.m., the day and date above set forth.

- - -

COMPUTER-AIDED TRANSCRIPTION BY
MORSE, GANTVERG & HODGE, INC.
PITTSBURGH, PENNSYLVANIA
412-281-0189

- - -

APPEARANCES:

On behalf of the Plaintiff:

Morgan Lewis:
John D. Zele, Esquire
1111 Pennsylvania Avenue, N.W.
Washington, D.C. 20004

On behalf of the Defendant:

Orrick Herrington & Sutcliffe:
Zheng Liu, Esquire
1000 Marsh Road
Menlo Park, California 94025

\- - -

ALSO PRESENT:

Carrie Molitierno, Videographer

\- - -

I-N-D-E-X

\- - -

THE VIDEOGRAPHER: This begins the deposition of Peter Munro. The time is 8:58 a.m.

We are on the record.

The court reporter may now swear the witness.

PETER MUNRO, Ph.D.

called as a witness by the plaintiff, having been first duly sworn, as hereinafter certified, was deposed and said as follows:

EXAMINATION

MR. ZELE: This is John Zele of Morgan Lewis Bockius for plaintiff, University of Pittsburgh.

MS. LIU: This is Zheng Liu from Orrick Herrington & Sutcliffe for defendant, Varian Medical Systems.

BY MR. ZELE:

Q Dr. Munro, would you say your name for the record?

A Yes. My name is Peter Munro.

Q And can you spell your last name?

A M-U-N-R-O.

Q And what is your home address?

A My home address is Pilger Strasse 215405 Baden-Dattwil in Switzerland.

Q You might have to spell out some of that.
A Right.
Pilger, P-I-L-G-E-R. And then Strasse is Street, S-T-R-A-S-S-E.
Baden is B-A-D-E-N.
And then hyphen, Dattwil is D-A-T-T-W-I-L.
Q Have you been deposed before?
A No.
I haven't.
Q Have you ever testified in a court of law?
A No.
Q Let me explain the procedure we go through in a deposition.
The first thing is you have been sworn in.
You have sworn to tell the truth, the whole truth, to the best of your ability.
Do you understand?
A Yes.
Q The second thing is you have to answer audibly.
Because the court reporter is going to be taking down your answers.
So he can't take down a nod of the head.
So if you can answer crisply and clearly, we would appreciate it.

A I guess you would have to be more specific in operation.

From a customer facing situation, yes.

I know what the customer would see.

In the details of the engineering, I have my bright spots.

And my blind spots.

Q And what is your role today?

A Again, it would help if somebody told me clearly.

Officially, my role hasn't changed.

I am still officially a product manager of on-board imager.

I am actually -- as my home address shows, I am relocated.

And that is the bulk of the engineering for the on-board imager is done in Switzerland.

And so I am now in much more close contact with the engineers.

So what that means is that I gave you that very long list of activities.

Now my focus tends to be much more on the customer requirement assessment.

And then converting that in to requirements for the engineers to develop.

And so the other roles are becoming less -- take less of my time.

Q Have you worked with products other than on-board imager?

A That is a little bit difficult question.

I would say in my role as a product manager, only on-board imager.

The on-board imager interacts with a lot of other product.

As I was mentioning, even other companies' products.

And so to the extent that I have had to work at the interfaces with other products, I have interacted with other products.

Q Which other products?

A Okay.

There are actually -- so there would be the Clinac.

There would be treatment planning systems.

I will use that plural. Varian has one that is called Eclipse.

But I have had to interact with other vendors' treatment planning systems as well.

The information system.

So that is, again, a wide variety of --

CERTIFICATE

COMMONWEALTH OF PENNSYLVANIA,)
) SS:
COUNTY OF ALLEGHENY.)

I, Lance E. Hannaford, do hereby certify that before me, a Notary Public in and for the Commonwealth aforesaid, personally appeared PETER MUNRO, PH.D., who then was by me first duly cautioned and sworn to testify the truth, the whole truth, and nothing but the truth in the taking of his oral deposition in the cause aforesaid; that the testimony then given by him as above set forth was by me reduced to stenotypy in the presence of said witness, and afterwards transcribed by means of computer-aided transcription.

I do further certify that this deposition was taken at the time and place in the foregoing caption specified, and was completed without adjournment.

I do further certify that I am not a relative, counsel or attorney of either party, or otherwise interested in the event of this action.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my seal of office at Pittsburgh, Pennsylvania, on this 24th day of October, 2007.

Lance Hannaford

Lance E. Hannaford
Notary Public
In and for the Commonwealth of Pennsylvania
My commission expires October 19, 2010

\- - -

EXHIBIT G

IN THE UNITED STATES DISTRICT COURT

WESTERN DISTRICT OF PENNSYLVANIA

--o0o--

CERTIFIED COPY

UNIVERSITY OF PITTSBURGH,

Plaintiff,

vs. No. 2:07-CV-00491-AJS

VARIAN MEDICAL SYSTEMS,

Defendant.

/

VIDEOTAPED DEPOSITION OF SAM DAVID CASTELLINO

THIS TRANSCRIPT HAS BEEN DESIGNATED CONFIDENTIAL

ATTORNEYS' EYES ONLY

Tuesday, October 16, 2007

REPORTED BY:

SUSAN F. MAGEE, RPR, CLR, CSR No. 11661

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IN THE UNITED STATES DISTRICT COURT

WESTERN DISTRICT OF PENNSYLVANIA

--o0o--

UNIVERSITY OF PITTSBURGH,

Plaintiff,

vs. No. 2:07-CV-00491-AJS

VARIAN MEDICAL SYSTEMS,

Defendant.

/

Videotaped deposition of SAM DAVID CASTELLINO taken on behalf of the Plaintiff, at Morgan, Lewis & Bockius, LLP, 2 Palo Alto Square 3000 El Camino Real, Suite 700, Palo Alto, CA 94306, beginning at 8:58 a.m. and ending at 10:14 a.m. on Tuesday, October 16, 2007, before me, SUSAN F. MAGEE, RPR, CLR, CSR No. 11661.

A P P E A R A N C E S :

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For the Defendant:

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(650) 614-7645 Fax (650) 614-7401
mheafey@orrick.com

The Videographer:

U.S. LEGAL SUPPORT

BY: RAMON PERAZA

180 Montgomery Street

Suite 2180

San Francisco, CA 94104

(415) 362-4346 Fax (415) 362-4495

Also Present:

JOHN L. HANSEN

MICHAEL CHEN

--o0o--

SAM DAVID CASTELLINO,

having been duly sworn, testified as follows:

EXAMINATION BY MR. PAUL

09:02:32

09:02:34 Q. Please state for the record your full name.

09:02:37 A. Sam David Castellino.

09:02:40 Q. Mr. Castellino, what is your business

09:02:40 address?

09:02:48 A. 911 Hansen Way, Building 3.

09:02:50 Q. And the company that you work for is?

09:02:53 A. Varian Medical Systems.

09:02:55 Q. What's your telephone number at Varian?

09:03:00 A. Which phone?

09:03:03 Q. Any direct line that you have is sufficient.

09:03:10 A. It's area code (650) 424-6669.

09:03:15 Q. And what are your home addresses?

09:03:27 A. 287 Hershner Court, Los Gatos, California.

09:03:30 Q. And any telephone numbers at the home

09:03:30 address?

09:03:32 A. Yes.

09:03:33 Q. And what is that?

09:03:40 A. (408) 879-9341.

09:03:43 Q. Have you ever had your deposition taken,

Mr. Castellino?

09:10:04 BY MR. PAUL: Q. Okay. And regarding the
09:10:09 unit count, will your answers for each of the devices
09:10:12 be similar in the sense that you don't know the unit
09:10:15 count for each of the devices?
09:10:17 MR. HEAFEY: Objection. Outside the
09:10:23 30(b)(6) designation. Vague and ambiguous.
09:10:23 THE WITNESS: Correct. I don't know the
09:10:24 unit count.
09:10:26 BY MR. PAUL: Q. Okay. That will save us a
09:10:30 little bit of time later. Let's go on to the OBI
09:10:33 product.
09:10:35 What documents in Varian's production
09:10:37 indicate where the OBI product is made?
09:10:39 MR. HEAFEY: Objection. Lacks foundation.
09:10:43 Vague and ambiguous.
09:10:45 THE WITNESS: There's several documents that
09:10:47 list the logistics. I don't know what the numbers
09:10:47 are.
09:10:49 BY MR. PAUL: Q. Okay. And where is the
09:10:51 OBI product made?
09:10:58 A. The OBI is kind of complex. You want to be
09:10:59 more specific?
09:11:07 Q. Okay. What are the components of the OBI
09:11:08 product?
MR. HEAFEY: Objection. Outside the scope

of the 30(b)(6) designation. Vague and ambiguous.

THE WITNESS: The OBI arms are manufactured in Baden, Switzerland. They're shipped to Varian Crawley. Varian Crawley purchases additional material and integrates and tests them, and then they're shipped from there.

BY MR. PAUL: Q. And what additional material is purchased by Varian and Crawley?

MR. HEAFEY: Objection. Outside the 30(b)(6) designation.

THE WITNESS: They purchase a generator, Paxscan panels. They purchase other material. I don't know -- I don't have a list of every one.

BY MR. PAUL: Q. Okay. Are you aware of any documents within the Varian production that would specify what Varian Crawley purchases

MR. HEAFEY: Objection. Outside the 30(b)(6) designation. Vague and ambiguous.

THE WITNESS: There would be drawings that would indicate that.

BY MR. PAUL: Q. Those drawings would indicate. Okay. And did you go over those documents in your preparation for this deposition?

MR. HEAFEY: Objection. Outside the 30(b)(6) designation.

your preparation for this deposition that tell us where the Portal Vision product is made?

A. No.

Q. No? Okay. And are you aware of where the Varian Portal Vision product is made?

MR. HEAFEY: Objection. Lacks foundation.

THE WITNESS: Yes.

BY MR. PAUL: Q. Okay. Where is the Varian Portal Vision product made?

A. Baden, Switzerland.

Q. Okay. Are there any other sites where the Portal Vision product is made?

A. No.

Q. Okay. Let's go to -- let's go back to the OBI product.

Are any of the OBI components manufactured in the United States?

MR. HEAFEY: Objection. Overly broad. Vague and ambiguous.

THE WITNESS: Fiberglass.

BY MR. PAUL: Q. Fiberglass. And what type of fiberglass is that?

MR. HEAFEY: Objection. Outside the scope of the 30(b)(6) designation. Vague and ambiguous.

THE WITNESS: This would be covers.

STATE OF CALIFORNIA) ss.
COUNTY OF ALAMEDA)

I, SUSAN F. MAGEE, RPR, CLR, a Certified Shorthand Reporter in and for the State of California and disinterested person, do hereby certify:

That prior to being examined, the deponent named in the foregoing deposition was by me duly sworn to testify the truth, the whole truth, and nothing but the truth;

That the said deposition was taken before me at the time and place therein stated and was thereafter transcribed into typewriting under my direction; that the foregoing deposition is a true record of the witness's testimony as reported by me; that the deponent was given an opportunity to read, correct and sign the deposition transcript.

I further certify that I am not related to any party or counsel or attorney for any of the parties in the foregoing deposition or in any way interested in the outcome of the action herein.

____
Susan F. Magee, RPR, CLR
CSR No. 11661